



THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

## Standards for Reporting Implementation Studies (StaRI) Statement

### Citation for published version:

Pinnock, H, Barwick, M, Carpenter, C, Eldridge, S, Grandes, G, Griffiths, C, Rycroft-Malone, J, Sheikh, A, Meissner, P, Murray, E, Patel, A, Sheikh, A & Taylor, SJC 2017, 'Standards for Reporting Implementation Studies (StaRI) Statement', *British Medical Journal (BMJ)*. <https://doi.org/10.1136/bmj.i6795>

### Digital Object Identifier (DOI):

[10.1136/bmj.i6795](https://doi.org/10.1136/bmj.i6795)

### Link:

[Link to publication record in Edinburgh Research Explorer](#)

### Document Version:

Peer reviewed version

### Published In:

British Medical Journal (BMJ)

### Publisher Rights Statement:

This is the author's peer-reviewed manuscript as accepted for publication.

### General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

### Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact [openaccess@ed.ac.uk](mailto:openaccess@ed.ac.uk) providing details, and we will remove access to the work immediately and investigate your claim.





## Standards for Reporting Implementation Studies (StaRI) Statement

Journal:	BMJ
Manuscript ID	BMJ.2016.034338.R1
Article Type:	Research methods and reporting
BMJ Journal:	BMJ
Date Submitted by the Author:	n/a
Complete List of Authors:	<p>Pinnock, Hilary; University of Edinburgh, Asthma UK Centre for Applied Research, Usher Institute for Population Health Sciences and Informatics, Barwick, Melanie; University of Toronto, Research Institute, Hospital for Sick Children; Department of Psychiatry and Dalla Lana School of Public Health,</p> <p>Carpenter, Christopher; Washington University in St. Louis, Department of Emergency Medicine</p> <p>Eldridge, Sandra; Queen Mary, University of London, Pragmatic Clinical Trials Unit, Centre for Primary Care and Public Health</p> <p>Grandes, Gonzalo; Basque Health Service, Primary Care Research Unit of Bizkaia,</p> <p>Griffiths, Chris; Queen Mary University of London, Centre for Primary Care and Public Health, Blizzard Institute</p> <p>Rycroft-Malone, Jo; Bangor University, Bangor Institute for Health &amp; Medical Research,</p> <p>Meissner, Paul; The University Hospital for Albert Einstein College of Medicine, Montefiore Medical Center,</p> <p>Murray, Elizabeth; University College London, Research Department of Primary Care and Population Health,</p> <p>Patel, Anita; Queen Mary University of London, Centre for Primary Care and Public Health, Blizzard Institute</p> <p>Sheikh, Aziz; University of Edinburgh, Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics,</p> <p>Taylor, Stephanie; Barts and The London School of Medicine and Dentistry, Queen Mary University of London, Centre for Primary Care and Public Health, Blizzard Institute</p>
Keywords:	Reporting standards, Implementation Science, Organizational innovation, Dissemination and implementation research, EQUATOR network

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

Confidential: For Review Only

## Standards for Reporting Implementation Studies (StaRI) Statement

Hilary Pinnock [hilary.pinnock@ed.ac.uk](mailto:hilary.pinnock@ed.ac.uk)  
Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh

Melanie Barwick [melanie.barwick@sickkids.ca](mailto:melanie.barwick@sickkids.ca)  
Research Institute, Hospital for Sick Children; Department of Psychiatry and Dalla Lana School of Public Health, University of Toronto

Christopher R. Carpenter [carpenterc@wustl.edu](mailto:carpenterc@wustl.edu)  
Washington University Division of Emergency Medicine. Washington University School of Medicine in St Louis

Sandra Eldridge [s.eldridge@qmul.ac.uk](mailto:s.eldridge@qmul.ac.uk)  
Pragmatic Clinical Trials Unit, Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Gonzalo Grandes [gonzalo.grandesodrizola@osakidetza.eus](mailto:gonzalo.grandesodrizola@osakidetza.eus)  
Primary Care Research Unit of Bizkaia, Basque Health Service

Chris J Griffiths [c.j.griffiths@qmul.ac.uk](mailto:c.j.griffiths@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Jo Rycroft-Malone [j.rycroft-malone@bangor.ac.uk](mailto:j.rycroft-malone@bangor.ac.uk)  
Bangor Institute for Health & Medical Research, Bangor University

Paul Meissner [pmeissne@montefiore.org](mailto:pmeissne@montefiore.org)  
Montefiore Medical Center, The University Hospital for Albert Einstein College of Medicine, New York

Elizabeth Murray [elizabeth.murray@ucl.ac.uk](mailto:elizabeth.murray@ucl.ac.uk)  
Research Department of Primary Care and Population Health, University College London

Anita Patel [anita.patel@qmul.ac.uk](mailto:anita.patel@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Aziz Sheikh [aziz.sheikh@ed.ac.uk](mailto:aziz.sheikh@ed.ac.uk)  
Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh

Stephanie JC Taylor [s.j.c.taylor@qmul.ac.uk](mailto:s.j.c.taylor@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

For the StaRI Group

### Members of the the StaRI Group are:

Melanie Barwick, Chris Carpenter, Peter Craig, Sandra Eldridge, Eleni Epiphaniou, Gonzalo Grandes Odrizola, Chris Griffiths, Martin Gulliford, Jo Rycroft-Malone, Paul Meissner, Brian Mittman, Elizabeth Murray, Anita Patel, Gemma Pearce, Hilary Pinnock, Aziz Sheikh and Steph Taylor.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Address for correspondence**

Professor Hilary Pinnock  
Asthma UK Centre for Applied Research, Usher Institute for Population Health Sciences and Informatics  
University of Edinburgh  
Doorway 3, Medical School, Teviot Place,  
Edinburgh EH8 9AG  
Tel: 0131 650 9474  
Fax: 0131 650 9119  
E-mail: [hilary.pinnock@ed.ac.uk](mailto:hilary.pinnock@ed.ac.uk)

Word count 2,145

## Abstract

Implementation studies are often poorly reported and indexed, reducing their potential to inform initiatives to improve healthcare services. The Standards for Reporting Implementation Studies (StaRI) initiative aimed to develop guidelines for transparent and accurate reporting of implementation studies. Informed by the findings of a systematic review and a consensus-building e-Delphi exercise, an international working group of implementation science experts discussed and agreed the StaRI Checklist comprising of 27 items. It prompts researchers to describe both the implementation strategy (techniques used to enhance promote implementation of an under-utilised evidence-based intervention) and the effectiveness of the intervention that was being implemented. An accompanying explanation and elaboration document details each of the items, explains the rationale and provides examples of good reporting practice. Adoption of StaRI will improve the reporting of implementation studies, potentially facilitating translation of research into practice and improving the health of individuals and populations.

## Summary box

- Unlike most reporting standards that apply to a specific research methodology, the StaRI Statement and accompanying Checklist refers to the broad range of study designs employed in implementation science.
- Underpinning the 27-item StaRI Checklist is the concept of dual strands describing, on the one hand, the strategies used to promote implementation and, on the other, the intervention being implemented.
- The expectation is that the authors will clarify both how they anticipate that the strategies employed are likely to promote implementation, and also explain the underpinning premise of why implementation of the intervention may be expected to improve healthcare or health outcomes.

- The requirement for extensive description of context, implementation strategies and interventions as well as reporting a broad range of effectiveness, process and health economic outcomes will challenge journals operating strict word limits for research papers and may require (innovative) solutions and use of supplementary online materials.

**Linked information**

StaRI website [url to be confirmed]

Enhancing the QUALity and Transparency Of health Research (EQUATOR) <http://www.equator-network.org/>

Consolidated Framework For Implementation Research (CFIR) <http://www.cfirguide.org/imp.html>

Logic models: <https://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide>

Dissemination and implementation models in Health Research and Practice.

<http://www.dissemination-implementation.org/index.aspx>

Process evaluation of complex interventions.

[https://www.ioe.ac.uk/MRC\\_PHSRN\\_Process\\_evaluation\\_guidance\\_final\(2\).pdf](https://www.ioe.ac.uk/MRC_PHSRN_Process_evaluation_guidance_final(2).pdf)

Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) <http://www.re-aim.hnfe.vt.edu>

**Keywords:** Dissemination and implementation research, EQUATOR Network, Implementation Science, Organizational innovation, Reporting standards.

Globally, healthcare systems are struggling to deliver the benefits of research to their populations.[1][w1-w3] Increasingly, it is recognised that translation from 'bench to bedside to community' [w4] is often ineffective and inefficient. The scientific community needs to focus on how effective interventions are disseminated and implemented across the spectrum of contexts and settings in order to improve individual and population health.[w5] Against this background, implementation science has emerged as an important discipline for developing the evidence base on how to translate research findings into routine care.[1-4]

Implementation studies are however often poorly reported and indexed, making it difficult to find, reproduce or synthesise the evidence from relevant studies.[5] More specific criticisms include poor (or absent) descriptions of conceptual frameworks underpinning the research,[5,6] inadequate description of context, and incomplete information about how the intervention was promoted and implemented (or not) in the different settings.[6][w6, w7] Similar concerns with, for example, the reporting of randomised controlled trials (RCTs) led to the introduction of the Consolidated Standards of Reporting Trials (CONSORT) checklist,[w8] with evidence of subsequent improvement in reporting standards.[w9-w11] There have been calls for the development of similar standards for transparent and accurate reporting of implementation studies.[5,6,7] The Standards for Reporting Implementation Studies (StaRI) initiative aimed to address this need.

### **Scope and relationship with other reporting standards**

Implementation science encompasses a broad range of methodologies applicable to improving the dissemination, implementation, and scaling-up of effective behavioural, clinical, healthcare, public health, global health and educational interventions,[8] (or discontinuation of ineffective or harmful practices,[w12]) with a view to improving quality of care and health outcomes. Although this document is set within the context of healthcare and population health, there are parallels in other



domains (such as educational initiatives).[9][w13] The StaRI Statement and Checklist may thus have resonance outside healthcare.

Understanding of the position that implementation studies hold in the science of developing, evaluating, disseminating and implementing healthcare interventions has been evolving over recent years. The UK Medical Research Council (MRC) Framework for Development and Evaluation of Complex Interventions [10] emphasises the need to disseminate and implement findings of complex interventions trials, but offers no advice on how to achieve this. PRECIS-2 conceives trial design on an ‘explanatory-pragmatic’ spectrum [11] but does not project beyond pragmatic trials to implementation in routine practice. Neither of these frameworks address the need for research to explore how interventions shown to be effective in trials require adaptation if they are to align with the routines of practice and be successfully implemented into ‘usual care’ settings.[12][w14-w17] Implementation science undertakes studies that explore healthcare contexts, develop and evaluate strategies for implementing effective interventions that address local realities, can be implemented at scale and are potentially sustainable.[2][w18] Proposed frameworks have added an ‘implementation cycle’ to complement the MRC’s complex intervention cycle,[13] or extended a linear spectrum (see Figure 1).[7,14] Others have emphasised the potential overlap between effectiveness and implementation research and described ‘hybrid’ designs.[15]

The StaRI Statement and Checklist aims to improve reporting of implementation studies, employing a range of study designs to develop and evaluate implementation strategies with the aim of enhancing adoption and sustainability of effective interventions.[16] This may be distinguished from quality improvement reports that describe system level initiatives, typically in the context of a specific problem within a specific healthcare system,[16][w19] and the World Health Organization guidelines which focus on improving reporting of their fieldwork.[w20]

## Methods

We followed the methodology described in the Developing Health Research Reporting Guidelines.[w21] Our full protocol is available on the EQUATOR website.[w22] Following a systematic literature review, we recruited international multidisciplinary experts (including healthcare researchers, journal editors, healthcare professionals and managers, methodologists, guideline developers, patient organisations, and funding bodies) to participate in an e-Delphi exercise.[17] Of 66 experts approached, 23 contributed suggestions for the Checklist, 20 completed the first scoring round and 19 completed the second scoring round. Of 47 potential items, 35 reached the *a priori* level of consensus for inclusion, i.e. 80% agreement with priority scores 7, 8 or 9: 19 items achieved 100% agreement. All these items, with their final priority scores, were taken forward as candidate items for inclusion in the StaRI Checklist.

In April 2015, we convened a 2-day consensus Working Group in London attended by 15 international delegates (UK/Europe=11; US/Canada=4) drawn from multiple disciplines. Delegates included healthcare researchers (n=9); journal editors (n=6), healthcare professionals (n=8) and managers (n=1), methodologists (n=4), guideline developers (n=2), and funding bodies (n=2) (several participants had more than one role). This group discussed the candidate items and agreed the first draft of the StaRI Checklist. The discussions were informed by the outcome of the e-Delphi exercise (see Appendix 1 for the e-Delphi results as provided to the workshop delegates), but items were also considered in the context of other published reporting standards and the wider literature, and the Group's expertise in implementation science. After general discussion on key defining concepts (informed by points raised in the e-Delphi[17]), each candidate item was considered in turn, Agreement was reached by discussion rather than by consensus scoring. The initial draft statement and documents were subsequently developed iteratively by e-mail discussion.

Constructive feedback on a penultimate draft of the StaRI statement from colleagues working internationally in the field of implementation science, healthcare researchers, clinicians and patients was used to help shape the final version of the paper. In addition, we have presented the concepts and sought feedback from several workshops, conference discussions and implementation project steering groups.

**Defining concepts**

There are two defining concepts underpinning the StaRI Statement and Checklist. The first is the dual strands of describing, on the one hand, the *implementation strategy* and, on the other, the clinical, healthcare, global health or public health *intervention* being implemented.[3, w23] For example, an implementation strategy (staff training, changes to invitation letters and appointment systems, development of computer templates, on-going audit etc.) might support an intervention (e.g. offering the option of telephone consultations) with the aim of improving access to routine asthma care.[w24] These strands are represented as two columns in the Checklist (see Table 1). The primary focus of implementation science is the implementation strategy [w25] and the expectation is that the items in column 1 will always be fully completed with details of how the intervention was implemented and the impact measured as an implementation outcome. The second strand (column 2) expects authors to complete items about the impact of the intervention on the health of the target population. This may be measured as a health outcome, or it may be more appropriate to cite robust evidence to support known beneficial effects of the intervention on health of individuals or populations (e.g. reducing smoking prevalence). Even when evidence is strong, the possibility that the impact of an intervention may be attenuated when it is implemented in routine practice needs to be considered. Whilst all items are worthy of consideration, not all items will be applicable to, or feasible in, every study; a fully completed StaRI Checklist may thus include a number of ‘not applicable’ items.

The second concept is that, unlike most reporting standards that apply to a specific research methodology, StaRI applies to the broad range of research methodologies employed in implementation science (for example, cluster RCTs, controlled clinical trials, interrupted time series, cohort, case study, before and after studies, as well as mixed methods quantitative/qualitative assessments).[3] Authors are referred to other reporting standards for advice on reporting specific methodological features – for example, randomisation in cluster RCTs,[w26] matching criteria in cohort studies,[w27] or addressing reflexivity in qualitative research.[w28]

### The StaRI Checklist

The StaRI Checklist comprises of 27 items of which 10 items expect authors to consider the dual strands of the implementation strategy and the intervention (see Table 1). Details about each of the Checklist items is provided in the accompanying Explanation and Elaboration document (see Appendix 2). Appendix 3 is a version of the checklist for completion by authors submitting an implementation paper. It is strongly recommended that authors using the StaRI Checklist read the detailed document that explains the rationale for each item and provides examples of good practice.

Three over-arching components are emphasised in the Checklist:

1. The expectation is that authors have an explicit hypothesis (we use the term 'logic pathway') that spans both how the implementation strategy is expected to work and the mechanism by which the intervention is expected to improve healthcare (see Appendix 2: Elaboration and Explanation document for a table of alternative terminologies and a link to a detailed description of 'logic models'.) This 'logic pathway' should reflect the rationale presented in the introduction, determine the approach to implementation, dictate implementation, health and process outcomes, and provide insights into why and how the implementation strategy and intervention worked (or not).

2. The balance between fidelity to, and adaptation of, the implementation strategy and intervention is of particular interest in implementation science. Fidelity refers to the degree of adherence to the described implementation strategy and intervention; adaptation is the degree to which users modify the strategy and intervention during implementation to suit the local needs. (see Table 2 for further description and examples). Insufficient fidelity to the ‘active ingredients’ of an intervention may dilute effectiveness,[w29] whereas insufficient adaptation or tailoring to local context may inhibit effective implementation.[18] An approach to reporting these apparently contradictory concepts is to define the core components of an intervention (ideally related to the logic pathway) to which fidelity is expected, and those aspects that may be adapted by local sites to aid implementation.[18] [w30]
3. Successful implementation of an intervention into practice is a planned, facilitated process involving the interplay between individuals, intervention or new ways of working, and context to promote evidence-informed practice.[19] A rich description of the context is critical to enable the reader to assess the external validity of the reported study,[w18] and to decide how the context in the study compares to their situation and if/how the implementation strategy can be directly transposed, or will need adapting.[w31] Similarly, social, political, and economic context influence the ‘entrenched practices’ that hinder evidence-based de-implementation of unproven practices or interventions.[w12,w32]

**Discussion**

Implementation science is an emerging and rapidly evolving field. The StaRI Statement and Checklist should therefore be seen as an evolving document, and potentially a catalyst for discussing and defining how implementation studies are conceived, planned and reported.[5]

We hope that the concept of dual strands will resonate with researchers designing and reporting implementation science studies. We appreciate that the distinction will not always be as

unambiguous as it appears in the StaRI checklist, but suggest that considering the design and evaluation of implementation studies in these two strands is helpful and aids clarity of study design and reporting. We also recognise that not all studies will measure health outcomes, though consideration of the ultimate goal of improving health through implementing an evidence-based intervention would seem a reasonable requirement. Feedback on both these underpinning concepts will be valuable for future iterations of the StaRI Statement and Checklist.

There are two practical challenges for the application of StaRI that warrant discussion. First, implementation science uses diverse methodologies that needed to be accommodated in the reporting standards. One option was to incorporate relevant items from other checklists, but this may be perceived as limiting the methodological options. StaRI therefore advises authors to consult methodological checklists for reporting design-specific aspects of their chosen study design. By doing this we have implicitly prioritised the concept underpinning implementation studies, though this should not be interpreted as undermining the rigour of reporting the chosen study design.

The second challenge is the requirement for extensive description of context, implementation strategies and interventions as well as reporting a broad range of primary effectiveness, process, health, economic and implementation outcomes.[w25] This will stimulate a debate about word counts, supplementary material and additional publications, which need to accommodate the journal requirements, author needs, and reader preferences. This tension is further discussed in the Explanation and Elaboration document, (see Appendix 2) and some practical approaches suggested for summarising information in tables or figures. We look forward to learning how authors and journals work with these challenges and the (innovative) solutions that they adopt (e.g. appendices, supplementary on-line files, additional publications).

## Conclusion

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

The StaRI Statement is registered with the EQUATOR Network [<http://www.equator-network.org> ] and the Checklist (for completion by authors) is freely available from BMJ.com (Appendix 3). We invite editors of all journals publishing implementation research to consider requiring submission of a StaRI Checklist, and authors reporting their implementation studies to use the Checklist. In the future we would like to work with authors as they apply the Checklist to their papers, ‘road testing’ the standards and enabling iterative development.

Previously published reporting guidelines have been instrumental in improving reporting standards [6][w8-w10] and our hope is that StaRI will achieve a similar improvement in the reporting of implementation strategies that will facilitate translation of effective interventions into routine practice, ultimately to benefit the health of individuals and populations.

**Competing interests:** All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: research grants from Chief Scientist Office (HP), Asthma UK (AS, HP, ST), Farr Institute (AS), NIHR HS&DR (HP, ST), NIHR CLAHRC (ST) for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; CC is Deputy Editor-in-Chief for Academic Emergency Medicine and on the editorial boards for the Journal of the American Geriatrics Society and Annals of Internal Medicine's ACP Journal Club and serves as paid faculty for Emergency Medical Abstracts, JR-M is Director of the NIHR HS&DR Programme, no other relationships or activities that could appear to have influenced the submitted work.

**Authors' contributions:** HP initiated the idea for the study and with ST led the development of the protocol, securing of funding, study administration, workshop and writing of the paper. AS, CG, and SE advised on the development of the protocol, and data analysis. All authors participated in the StaRI international working group along with GP, BM, MG. HP wrote the initial draft of the paper, to which all the authors contributed. HP is the study guarantor.

**Funding:** The StaRI initiative and workshop was funded by contributions from the Asthma UK Centre for Applied Research [AC-2012-01]; Chief Scientist Office, Scottish Government Health and Social Care Directorates [PCRCA\_08\_01]; the Centre for Primary Care and Public Health, Queen Mary University of London; and with contributions in kind from the PRISMS team [NIHR HS&DR Grant ref: 11/1014/04]. ST was (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. AS is supported by the Farr Institute. The funding bodies had no role in the design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; nor in the decision to submit the manuscript for publication.

**Disclaimers:** The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

**Acknowledgements:** Members of the PRISMS team (Eleni Epiphaniou, Gemma Pearce, and Hannah Parke) supported the underpinning literature work, and the e-Delphi was handled by ClinVivo. We are grateful to a colleagues (implementation science experts, healthcare researchers, clinicians, PhD students) who reviewed the penultimate draft of the StaRI statement and provided a reality check and constructive feedback: Helen Ashdown, David Chambers, Louise Craig, Clarisse Dibao-Dina, Peter Hanlon, Roger Jones, Rachel Jordan, Chris del Mar, Brian McKinstry, Susan Morrow, John Ovreteit, David Price, Kamran Siddiqui, Rafael Stelmach, Paul Stephenson, Shaun Treweek, Bryan Weiner. We also thank Melissa Goodbourn and Allison Worth who arranged feedback from the Edinburgh Clinical Research Facility Patient Advisory Panel (Stephanie Ashby, Alison Williams) and Steven Towndrow who co-ordinated feedback from the Patient and Public Involvement representatives of the NIHR CLAHRC North Thames.

**Provenance of the paper:** The StaRI checklist was informed by the findings of a literature review and an e-Delphi, an international consensus workshop and the subsequent e-mail correspondence amongst members of the StaRI group. The international authors contributed expertise on clinical practice, public health, knowledge exchange, implementation science, complex interventions and a range of methodologies including quantitative and qualitative evaluations.

**Copyrights statement:** The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, a worldwide licence to the Publishers and its licensees in perpetuity, in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution, iii) create any other derivative work(s) based on the Contribution, iv) to exploit all subsidiary rights in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above



References

1. Chalkidou K, Anderson G. *Comparative Effectiveness Research: International Experiences and Implications for the United States*. Available from [http://www.nihcm.org/pdf/CER\\_International\\_Experience\\_09.pdf](http://www.nihcm.org/pdf/CER_International_Experience_09.pdf) (Accessed June 2016)

2. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50

3. Peters DH, Adam T, Alonge O, Akua Agyepong I, Tran N. Implementation research: what it is and how to do it. *BMJ* 2013;347:f6753

4. Foy R, Sales A, Wensing M, et al. Implementation science: a reappraisal of our journal mission and scope. *Implement Sci* 2015;10:51

5. Pinnock H, Epiphaniou E, Pearce G, et al. Implementing supported self-management for asthma: a systematic review of implementation studies. *BMC Medicine* 2015;13:127

6. Rycroft-Malone J, Burton CR. Is it time for standards for reporting on research about implementation? *Worldviews Evid Based Nurs* 2011;8:189-90

7. Neta G, Glasgow RE, Carpenter CR, et al. A Framework for Enhancing the Value of Research for Dissemination and Implementation *Am J Public Health* 2015;2105:49-57

8. Brownson RC, Colditz GA, Proctor EK (eds) *Dissemination and implementation research in health: translating science into practice*. New York; Oxford University Press: 2012

9. Barwick M, Barac R, Akrong LM, Johnson S, Chaban P. Bringing evidence to the classroom: exploring educator notions of evidence and preferences for practice change. *Int J Educ Res* 2014;2:1-15

10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. London:

MRC; 2008. Available from [www.mrc.ac.uk/complexinterventionsguidance](http://www.mrc.ac.uk/complexinterventionsguidance) [accessed June 2016]

11. Loudon K, Treweek S, Sullivan F, et al. The PRECIS-2 tool: designing trials that are fit for purpose *BMJ* 2015;350:h2147
12. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Millbank Q.* 2004; 82:581–629
13. Pinnock H, Epiphaniou E, Taylor SJC. Phase IV implementation studies: the forgotten finale to the complex intervention methodology framework. *Annals ATS* 2014;11:S118–22
14. Lansdverk J, Brown CH, Chamberlain P et al. Chapter 12. Design and analysis in dissemination and implementation research, in Brownson RC, Colditz GA, Proctor EK (eds) *Dissemination and implementation research in health: translating science into practice*. New York: Oxford University Press 2012
15. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact. *Medical Care* 2012;50:217-226
16. Bauer MS, Damschroder L, Hagedorn H, et al. An introduction to implementation science for the non-specialist. *BMC Psychology* 2015;3:32
17. Pinnock H, Epiphaniou E, Sheikh A, et al. Developing Standards for Reporting Implementation studies (StaRI): an e-Delphi. *Implement Sci* 2015;10:42
18. Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a randomised controlled trial be? *BMJ* 2004;328:1561–3

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

19. Rycroft-Malone J, Seers K, Chandler J, et al. The role of evidence, context, and facilitation in an implementation trial: implications for the development of the PARIHS framework. *Implement Sci* 2013;8:28

Confidential: For Review Only

## Figures and Tables

**Figure 1. Positioning of implementation studies and the focus of StaRI reporting standards.** (Adapted from Figure 12.1. in Brownson et al[8])

Note: StaRI is targeted on the reporting of interventional implementation studies (the dark shaded box) but will have resonance for studies in the pilot and sustainability phases

Table 1. Standards for Reporting Implementation Studies: the StaRI Checklist

Report the following:		“Implementation strategy” refers to how the intervention was implemented. “Intervention” refers to the healthcare or public health intervention that is being implemented.	
Checklist item		Implementation Strategy	Intervention
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords	
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.	
Introduction	3	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.	
	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.	
Methods: description	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	7	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).	
	8	The characteristics of the targeted ‘site(s)’ (e.g. locations/personnel/resources etc.) for implementation and any eligibility criteria.	The population targeted by the intervention and any eligibility criteria.
	9	A description of the implementation strategy	A description of the intervention
	10	Any sub-groups recruited for additional research tasks, and/or nested studies are described	
Methods: evaluation	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
	12	Process evaluation objectives and outcomes related to the mechanism(s) through which the strategy is expected to work	

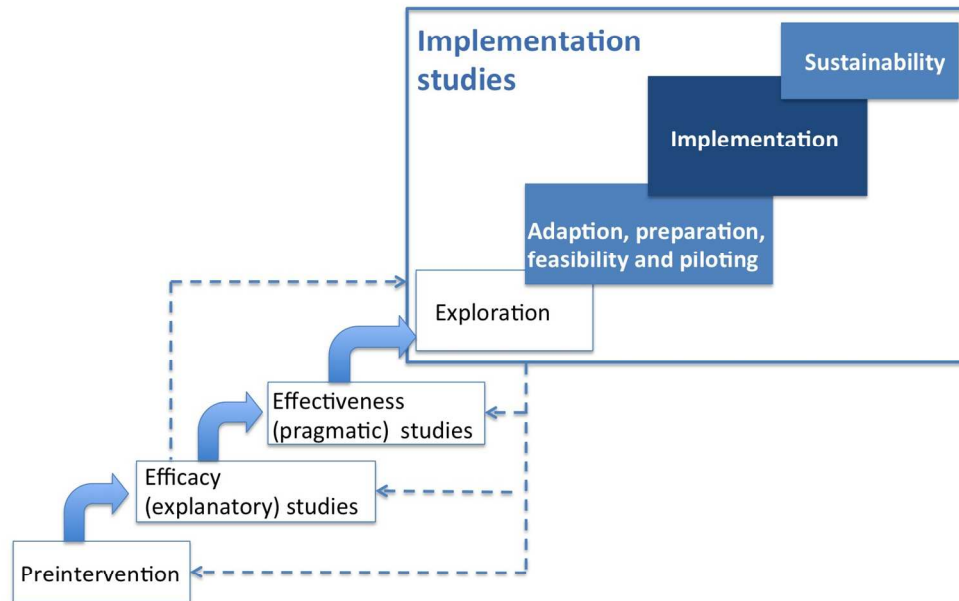
	<b>13</b>	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	Methods for resource use, costs, economic outcomes and analysis for the intervention
	<b>14</b>	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)	
	<b>15</b>	Methods of analysis (with reasons for that choice)	
	<b>16</b>	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks	
<b>Results</b>	<b>17</b>	Proportion recruited and characteristics of the recipient population for the implementation strategy.	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
	<b>18</b>	Primary and other outcome(s) of the implementation strategy.	Primary and other outcome(s) of the Intervention (if assessed).
	<b>19</b>	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work	
	<b>20</b>	Resource use, costs, economic outcomes and analysis for the implementation strategy	Resource use, costs, economic outcomes and analysis for the intervention
	<b>21</b>	Representativeness and outcomes of subgroups including those recruited to specific research tasks	
	<b>22</b>	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	Fidelity to delivering the core components of intervention (where measured).
	<b>23</b>	Contextual changes (if any) which may have affected outcomes	
	<b>24</b>	All important harms or unintended effects in each group.	
<b>Discussion</b>	<b>25</b>	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications.	
	<b>26</b>	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability).	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability).
<b>General</b>	<b>27</b>	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest.	

Note: A key concept is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist. The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. Whilst all items are worthy of consideration, not all items will be applicable to or feasible within every study.

Table 2. Terminology: Definitions and illustration

Terminology	Definition	Illustration using a study implementing supported self-management for asthma
Implementation science	The scientific study of methods to promote the systematic uptake of evidence-based interventions into practice and policy and hence improve health.[4]	Improving implementation in routine practice of evidence-based supported self-management for asthma
Implementation strategy	Methods or techniques used to enhance the adoption, implementation, and sustainability of an under-utilised intervention.[15][w26]	A programme of professional training, templates for reviews, access to resources, facilitation, audit and feedback.
Intervention	The evidence-based practice, programme, policy, process, or guideline recommendation that is being implemented.[8]	Provision of asthma self-management in routine asthma reviews, including completion of action plans.
Implementation outcome	Process or quality measure to assess the impact of the implementation strategy.[w24]	Proportion of people with asthma who have an action plan.
Health outcome	Patient-level health outcomes for a clinical intervention, such as symptoms or mortality; or population-level health status or indices of system function for a system/ organisational-level intervention.[15]	Proportion of people with asthma requiring unscheduled care for asthma or patient reported asthma control.
Logic pathway	The way(s) in which the implementation strategy and intervention are hypothesised to operate.	An organisation that prioritises self-management encourages/enables trained professionals to provide asthma action plans; self-management improves asthma outcomes
Fidelity	The degree of adherence to the described implementation strategy and/or the degree to which an intervention is implemented as prescribed in the original protocol.[w29]	Uptake of professional training, utilisation of review templates (implementation fidelity) and assessment of adequacy of education and completion of action plans (intervention fidelity)
Adaptation	The degree to which the strategy and intervention are modified by users during implementation to suit the local needs.[18]	Use (or not) of telehealth to deliver reviews or provide action plans. Different professionals (doctors/ nurses/ pharmacists) with primary responsibility for self-management education

Figure 1. Positioning of implementation studies and the focus of StaRI reporting standards.  
(Adapted from Figure 12.1. in Brownson et al[ref 8])



StaRI is targeted on the reporting of interventional implementation studies (the dark shaded box) but will have resonance for studies in the pilot and sustainability phases.

Positioning of implementation studies and the focus of StaRI reporting standards. (Adapted from Figure 12.1. in Brownson et al[8])

595x446mm (72 x 72 DPI)



Note: Green items reached consensus in the e-Delphi; black items did not reach consensus

Discussion session 1: Introduction

Checklist item		Consensus: % agreement with scores 7-9. Second round,(first round)	Item specific comments: First round; Second round
3	Identify the aspect of care that the new service being implemented aims to address (e.g. implementing a guideline recommendation or evidence-based management)	90%,(89%)	
4	Critically report the evidence underpinning the new service to be implemented: (e.g. phase III randomised controlled trials, systematic review, guideline recommendations)	100%, (90%)	
5	Include a description of the wider healthcare/policy/commercial context	58%, (55%)	
6	Describe the rationale for the new service design	(95%), (85%)	<ul style="list-style-type: none"><li>re 6. - this may also be an important aspect of the research i.e. to understand the rationale for the new service design - and how these may differ between different stakeholders</li></ul>
7	Report the implementation strategy used and its underpinning theory	(84%) (80%)	<ul style="list-style-type: none"><li>Item #7 might be rather part of the methodology section. However, its underpinning theory is rather part of the introduction. So, this might be split: methodology in that section, but implementation theory in the intro.</li><li>For # 7 - theory could be theories and might change wording to say and mention it underpinning theory(ies)</li><li>implementation strategy might be better placed in methods</li><li><b>#7 Report the implementation strategy used and its underpinning theory: for me this may also be described in the methods section. It should be somewhere in the paper</b></li></ul>
8	Describe any pilot implementation work and the conclusions from that work	(63%), (60%)	<ul style="list-style-type: none"><li>Item #8 should be included if available. It adds to why the study needed to been done.</li></ul>
9	Clearly define the aims of the study, differentiating between implementation (process) objectives and	(100%), (90%)	<ul style="list-style-type: none"><li>Re question 9 - depending on the nature of intervention - the outcomes may not be clinical (e.g. if an organisational</li></ul>

	effectiveness (clinical) objectives aims		intervention the summative outcomes may be service design orientated or practitioner behaviour orientated). I am making an assumption the standards that result from this process should be as widely applicable as possible. <ul style="list-style-type: none"><li>re 9. - this assumes as per round 1 that the implementation of the new service is carried out at the same time as the evaluation and by same people - it may not</li></ul>
Wider context	<ul style="list-style-type: none"><li>This part describes the background of any study in which items #3-6 and #9 should be included. Also the (non-)involvement of stakeholders should be addressed. Relates to item #10.</li></ul>		

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49

Discussion sessions 2: Methods part I (Setting, The new service)

Checklist item (Setting)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>
10	Describe the study setting (including health service, personnel involved, patient and public involvement, demography of patients etc)	(100%), (100)	<ul style="list-style-type: none"><li>• PPI: describe at what level (tokenism; "subject" = volunteer; advisor).</li><li>• Ideally, the study design includes the interactive collaboration and dialogue with stakeholders for a priori study improvement, study progress issues and discussion on outcome/valorisation. If not included, this should be explained.</li><li>• Again, q10. - + these issues may form part of the research</li></ul>
11	Give year(s) during which the new service was implemented (i.e. planned, initiated and actively developed) and followed up	(95%), (80)	<ul style="list-style-type: none"><li>• q.11 - assumes this is straightforward - implementation usually messy and happens over a period of time - that needs to be acknowledged</li><li>• <b>As outcomes change over time for many diseases this is essential to my mind</b></li><li>• <b>the implementation of the new service in which period might be useful given the current changes in healthcare. In the stated period the implementation might have been more (un)successful than in another timeframe.</b></li></ul>
		?include an formal assessment made of the context before deciding on an implementation intervention	
		Ultimately, the checklist that results from this delphi process will require specific examples from the implementation science literature to inform authors/editors how to fulfill these recommendations. For example, "Describe the study setting" seems quite vague currently, but is a very important element of transparent reporting in D&I research.	
		OK, I am persuaded...	
Checklist item (The new service)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>
12	Describe the new service (e.g components/content, frequency, duration, intensity, mode of delivery, materials used) with advice on accessing additional detailed information. Use of a standardised checklist	(100%), (100)	

	(e.g. TiDieR) is recommended.		
13	Describe the professional backgrounds, roles and training requirements of the personnel involved in delivering the intervention with advice on accessing additional detailed information.	(84%), (65)	<ul style="list-style-type: none"> <li>part of items (#13, #17) can also be described in addendum. A brief description in the main methodology section, and more details in the addendum.</li> <li><b>Professional training has a wide spread but without this information it is really hard to know if staff in your own context has the skill base required to deliver the intervention</b></li> </ul>
14	Define the core components of the intervention, and the processes for assessing fidelity to this core content, and what, if any, local adaptation was allowed.	(100%), (90)	<ul style="list-style-type: none"> <li>On item 14, fidelity and adaptation allowed are really two different constructs, not necessarily the mirror image of the other.</li> </ul> <p>#14 is duplicative of #12. They should be merged.</p>
15	Describe the intervention received by control/comparator group not simply stating 'usual care'	(95%), (75)	Describe the intervention received by control/comparator This could be difficult as in a cluster trial may be very different from place to place
16	What is the relation of components of the intervention to the rationale for the new service design and/or theory underpinning implementation discussed above?	(30%), (21)	I'm not sure whether theory should be given in the methodology section. If briefly described (one-two sentences): yes. Otherwise, embedding in the introduction may be better suited.
17	Define role of the researchers in design and implementation.	(79%), (60)	<ul style="list-style-type: none"> <li>17 is confusing. Do you mean in program d &amp; l or research d &amp; i?</li> </ul> <p>17 possibly only necessary if they were involved</p>
Change over time		Need to allow for change in intervention over time as well as local adaptability – these q's assume new service is fixed in aspic	
Usual care		<b>The control intervention needs to be described as "usual care" in one clinical setting may differ from another. Components of the new strategy may be part of the "usual care" given in one centre but not in another. It is important to know whether the intervention works/is efficient/effective, but what makes it precisely working needs to be known.</b>	

Discussion session 3: Methods part II (Population, randomisation, data, analysis)

Checklist item (Population)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>
18	Describe sites invited/excluded with reasons	(100%), (95)	item #18: in- or exclusion criteria of sites should be given, as well as which sites were included. This may also be part of an addendum to the methodology section
19	Describe the population targeted by the intervention and any eligibility criteria	(100%), (95)	
20	Report method by which patients are referred to, or access the new service.	(100%), (90)	<ul style="list-style-type: none"><li>#21 confusing as written "what if consent for data collection, but not intervention?"</li></ul>
21	If applicable, describe any consent required (which should be to the new service and not to research)	(53%), (60)	
22	Describe recruitment of any sub-groups recruited for additional research-tasks (e.g. questionnaire completion, physiological measures, detailed record analysis)	(47%), (55)	<ul style="list-style-type: none"><li>22 seems off topic to me if this is in relation to programming.</li><li>I don't understand the wording of #22.</li><li>#22: for any new research the sub-groups should be described in detail. Otherwise the study and related analysis is scientifically not sound/repeatable.</li></ul>
		These items get at but do not precisely describe the characteristics of those who end up participating- and contrasting those who participate with those who decline- at both the setting and the individual patient level	
Checklist item (Randomisation)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>
23	Description of randomisation (or if not randomised how comparator group was selected)	(95%), (85)	<ul style="list-style-type: none"><li>part of methodology, needed for repetition of the study elsewhere. However, an extensive description fits an addendum to the methodology section, not the main core of this section</li><li>Important, but covered in other guidelines</li></ul>
Checklist item (Data)		Consensus: % agreement with scores 7-9. <b>Second</b>	Item specific comments: First round; <b>Second round</b>

		round,(first round)	
24	Describe outcome measurements (specifically describing any that are at population level) distinguishing between process and clinical outcomes, health economic data	(100%), (100)	
25	Describe data collection processes (specifically including methods of extracting routine data).	(100%), (90)	
26	Describe any processes for quality assurance (especially for use of routine data)	(84%), (65)	<ul style="list-style-type: none"> <li>Item #26: to be described in brief terms in main core of this section. Can be described more extensively in addendum. Or may be referred to if described in another scientific or openly available publication.</li> <li>#26: may also be given in an addendum to the paper.</li> </ul>
Checklist item (Analysis)		Consensus: % agreement with scores 7-9. Second round,(first round)	Item specific comments: First round; Second round
27	Describe power calculation and rationale for sample size	(100%), (90)	
28	Describe methods of statistical analysis (with reasons for that choice) including approach to clustering, handling of missing data, intention to treat analysis, and adjustment for confounders etc)	(100%), (90)	
29	Specify <i>a priori</i> sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations)	(95%), (85)	<ul style="list-style-type: none"> <li>Agree with item #29, but may be brief in main core of this section and extended in addendum.</li> <li>#29: any analysis regarding primary and secondary outcome should be defined on beforehand. Other analyses may be derived from the (unexpected?) results. Therefore, I rate this question a bit higher</li> </ul>
		<ul style="list-style-type: none"> <li>Above are all important, but covered in other guidelines- should be integrated with others</li> <li>One of the struggles to develop unique D&amp;I reporting guidelines highlighted by the United States' NIH efforts to do what StaRI is undertaking is pertinent here. There are over 25 guidelines archived on the EQUATOR network already. Some of them have components applicable to D&amp;I research (for example the methods section of the CONSORT Pragmatic trial guidelines). Our NIH group argued whether it would be better to refer D&amp;I investigators to existing publication guidelines sometimes</li> </ul>	

Discussion session 4: Results

Checklist item (Population)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>
30	Report the number of sites approached, reasons for non-participation, and characteristics of participating sites	(89%), (75)	<ul style="list-style-type: none"><li>#30 is duplicative of #18. These should be merged.</li></ul>
31	Report the total eligible population (e.g. number of people with the relevant condition registered with the practice, or eligible for a service), number approached and any exclusions	(100%), (90)	<ul style="list-style-type: none"><li>It is important to try and report the eligible population though this might sometimes be tricky to know (e.g.. when recruiting in the community rather than through the health service). Still, an attempt would be appreciated.</li></ul>
32	Report participation rate among the eligible population, compare characteristics with the eligible population as a whole, and describe any known reasons for non-participation.	(95%), (75)	<ul style="list-style-type: none"><li>32 can be difficult data may not be available</li></ul>
33	Report compliance with/attrition from the service as a process outcome	(95%), (85)	<ul style="list-style-type: none"><li>Item #33 deals with why people were not compliant with the study. This might complicate the research ethics procedure (people may withdraw at any moment w/o giving a reason).</li><li>33. not sure this is essential</li><li>q.33 - don't think 'compliance' is appropriate term here - participation would be better</li></ul>
34	Report details of any subgroups recruited to specific research tasks (e.g. questionnaire completion, physiological testing) as opposed to the clinical service. Compare characteristics of any sub-groups to the whole eligible population	(74%), (70)	
35	Include a CONSORT diagram (modified as necessary) to illustrate the recruitment of sites, provision of service to patients, and any sub-groups	(84%), (80)	<ul style="list-style-type: none"><li>Item #35: would be profitable. But not necessary per se</li></ul>
In the ideal situation we like to see all of the data stated above.			
Checklist item (Fidelity)		Consensus: % agreement with scores 7-9. <b>Second round</b> , <sub>(first round)</sub>	Item specific comments: First round; <b>Second round</b>

36	Report fidelity to the core components of the planned intervention (including, in multicentre studies, in the different settings)	(100%), (85)	<ul style="list-style-type: none"> <li>Important, but fidelity is a very complex construct and probably needs reporting standards of its own</li> <li>Again, good to report fidelity but if measuring it might affect it (ie. the act of observation changes fidelity) then perhaps it's less meaningful than we might think. Important to try if possible though.</li> </ul>
37	Report any modifications or adaptations to the new service during the course of the study	(100%), (95)	<ul style="list-style-type: none"> <li>#37 - would add significant before modifications need to provide an analysis of why as well as what modifications/adaptations made</li> </ul>
Overlap with earlier items- very important to report both fidelity and adaptations/ variations separately and non judgmentally			
Checklist item (Outcomes)		Consensus: % agreement with scores 7-9. Second round, (first round)	Item specific comments: First round; Second round
38	Report outcomes for the whole eligible population, before an analysis of any sub-groups	(100%), (85)	
39	Report process and clinical outcomes	(100%), (95)	
40	If relevant, report impact on use of health service resources (and ideally cost of the intervention)	(84%), (70)	<ul style="list-style-type: none"> <li>Item #40: involves HTA. This can be included in the study design, but needs to be stated in e.g. methodology. If HTA is taken along as stakeholder (not partner), this may rather be part of the discussion.</li> </ul>
41	Report any unintended consequences, or adverse effects	(100%), (95)	



Discussion session 5: Discussion, Abstract, General

Checklist item (Population)		Consensus: % agreement with scores 7-9. Second round,(first round)	Comments
42	Include a structured abstract (for example including summary of findings, strengths and limitations, comparison with other studies, conclusions and implications)	(58%), (55)	<ul style="list-style-type: none"><li>I didn't understand 'structured abstract' in question 42. I assume this means structured summary</li><li>Not sure how I feel about structured abstracts for the Discussion. I could be persuaded although maybe a 'Results in context' box would be better.</li><li>#42 is duplicative of #2.</li></ul>
43	Reflect on the processes of implementing the service, barriers or facilitators, and lessons learned	(79%), (75)	
44	How did the setting enable or hinder the implementation of the new service	(79%), (60)	<ul style="list-style-type: none"><li>To me item #44 relates to item #43. It seems to be part of item #43. As such, I rated #44 lower (not unnecessary).</li><li>44. Can be quite subjective especially for people bought into the idea of a new service</li></ul>
45	How was the new service was implemented highlighting (if relevant) variations between sites and over time and the impact on treatment outcomes and unintended consequences	(74%), (60)	<ul style="list-style-type: none"><li>45. may be in results</li><li>Item 45 seems redundant with the others- if report on them, not sure need it</li></ul>
46	Interpret findings in the light of the general body of literature, and consider implications for healthcare services (including issues of generalizability, transferability, strategies for facilitating and normalising into routine care)	(100%), (80)	
		<ul style="list-style-type: none"><li>Include interpretation in relation to theory - reflecting back on the theory underpinning the intervention reported/stated earlier</li><li>q's 43, 44, 45 - relevant data on these should be in findings, not just reflected on in discussion</li></ul>	
Checklist item (Title and abstract)		Consensus: % agreement with scores 7-9. Second round,(first round)	Item specific comments: First round; Second round
1	The title (or abstract if word count of title precludes) should include a description of the methodology (e.g.	79%, (80%)	

	phase IV implementation study, cluster randomised implementation trial, interrupted time series, before and after, stepped wedge study)		
2	There should be a structured abstract which clearly states aim, study design, setting, population, intervention, outcomes, conclusion and implications.	95%, (95%)	
	<ul style="list-style-type: none"> <li>This seems a very general standard, nothing specific to these studies</li> </ul>		
Checklist item (General)		Consensus: % agreement with scores 7-9. <b>Second round</b> , (first round)	Item specific comments: First round; <b>Second round</b>
47	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration, funding and conflicts of interest.	(89%), (75)	#47 mixes up many different topics- some like registration and COI are critical; others much less so
General comments			
	I would also like to know if they had any stakeholder advisory group and how they engaged with them - for what purposes, with what frequency.		
	<ul style="list-style-type: none"> <li>These are covered under other guidelines</li> </ul>		
	Sorry, lots of essentials in my response. Hard to say much shouldn't be there really, good suggestions for a reporting standard.		

**Standards for Reporting Implementation Studies (StaRI)**  
**Explanation and Elaboration document**

Hilary Pinnock [hilary.pinnock@ed.ac.uk](mailto:hilary.pinnock@ed.ac.uk)  
Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh

Melanie Barwick [melanie.barwick@sickkids.ca](mailto:melanie.barwick@sickkids.ca)  
Research Institute, Hospital for Sick Children; Department of Psychiatry and Dalla Lana School of Public Health, University of Toronto.

Christopher R. Carpenter [carpenterc@wustl.edu](mailto:carpenterc@wustl.edu)  
Washington University Division of Emergency Medicine. Washington University School of Medicine in St Louis

Sandra Eldridge [s.eldridge@qmul.ac.uk](mailto:s.eldridge@qmul.ac.uk)  
Pragmatic Clinical Trials Unit, Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Gonzalo Grandes [gonzalo.grandesodrizola@osakidetza.eus](mailto:gonzalo.grandesodrizola@osakidetza.eus)  
Primary Care Research Unit of Bizkaia, Basque Health Service

Chris J Griffiths [c.j.griffiths@qmul.ac.uk](mailto:c.j.griffiths@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Jo Rycroft-Malone [j.rycroft-malone@bangor.ac.uk](mailto:j.rycroft-malone@bangor.ac.uk)  
Bangor Institute for Health & Medical Research, Bangor University

Paul Meissner [pmeissne@montefiore.org](mailto:pmeissne@montefiore.org)  
Montefiore Medical Center, The University Hospital for Albert Einstein College of Medicine, New York

Elizabeth Murray [elizabeth.murray@ucl.ac.uk](mailto:elizabeth.murray@ucl.ac.uk)  
Research Department of Primary Care and Population Health, University College London

Anita Patel [anita.patel@qmul.ac.uk](mailto:anita.patel@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Aziz Sheikh [aziz.sheikh@ed.ac.uk](mailto:aziz.sheikh@ed.ac.uk)  
Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh

Stephanie JC Taylor [s.j.c.taylor@qmul.ac.uk](mailto:s.j.c.taylor@qmul.ac.uk)  
Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

For the StaRI Group

**The StaRI Group includes:**  
Melanie Barwick, Chris Carpenter, Peter Craig, Sandra Eldridge, Eleni Epiphaniou, Gonzalo Grandes Odrizola , Chris Griffiths, Martin Gulliford, Jo Rycroft-Malone , Paul Meissner, Brian Mittman, Elizabeth Murray, Anita Patel, Gemma Pearce, Hilary Pinnock, Aziz Sheikh and Steph Taylor.

**Address for correspondence**

Professor Hilary Pinnock

Asthma UK Centre for Applied Research, Usher Institute for Population Health Sciences and Informatics

University of Edinburgh

Doorway 3, Medical School, Teviot Place,

Edinburgh EH8 9AG

Tel: 0131 650 9474

Fax: 0131 650 9119

E-mail: [hilary.pinnock@ed.ac.uk](mailto:hilary.pinnock@ed.ac.uk)

Word count 4,992 (excluding the examples)

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Abstract**

**Objectives:** Implementation studies are often poorly reported and indexed, reducing their potential to inform the provision of healthcare services. The Standards for Reporting Implementation Studies (StaRI) initiative aims to develop guidelines for transparent and accurate reporting of implementation studies.

**Methods:** An international working group developed the StaRI guideline informed by a systematic literature review and e-Delphi prioritisation exercise. Following a face-to-face meeting, the checklist was developed iteratively by e-mail discussion and critical review by international experts.

**Results:** The 27 items of the checklist are applicable to the broad range of study designs employed in implementation science. A key concept is the dual strands, represented as two columns in the checklist, describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention being implemented. This explanation and elaboration document details each of the items, explains the rationale and provides examples of good reporting practice.

**Conclusion:** Previously published reporting statements have been instrumental in improving reporting standards; adoption by journals and authors may achieve a similar improvement in the reporting of implementation strategies that will facilitate translation of effective interventions into routine practice.

**Keywords:** Dissemination and implementation research, EQUATOR Network, Implementation Science, Organizational innovation, Reporting standards

Implementation science bridges the gap between developing and evaluating effective interventions and implementation in routine practice to improve patient and population health.[1] Implementation studies are however often poorly reported and indexed,[2,3] reducing their potential to inform the provision of healthcare services and improve health outcomes.[4] The Standards for Reporting Implementation Studies (StaRI) initiative aimed to develop standards for transparent and accurate reporting of implementation studies. The StaRI statement describing the scope and conceptual underpinning is published in the *BMJ*:[5] this elaboration document provides detailed explanation of the individual items.

## Methods

Following established guidelines,[6,7] we convened a consensus working group in London at which 15 international multidisciplinary delegates considered candidate items identified by a previous systematic literature review and an international e-Delphi prioritisation exercise,[8] in the context of other published reporting standards and the panel's expertise in implementation science. The resultant checklist was subsequently developed iteratively by e-mail discussion, and feedback on the penultimate draft guideline sought from colleagues working in implementation science.

## Scope of the StaRI reporting standards

Implementation research is the scientific study of methods to promote the systematic uptake of evidence-based interventions into practice and policy and hence improve health. [9-11] The discipline encompasses a broad range of methodologies applicable to improving the dissemination and implementation of clinical, healthcare, global health and public health interventions.[12-14] The StaRI checklist focuses primarily on standards for reporting studies that evaluate implementation strategies developed to enhance the adoption, implementation, and sustainability of interventions,[15] but some items may be applicable to other study designs used in implementation science.

**The StaRI reporting guidelines**

Unlike most reporting guidelines that apply to a specific research methodology, StaRI is applicable to the broad range of study designs employed in implementation science. Authors are referred to other reporting standards for advice on reporting specific methodological features. In an evolving field, in which there is a range of study designs, terminology is neither static nor used consistently.[16] For clarity, we have adopted specific terms in this paper; Table 1 defines these terms and lists some of the alternative or related terminology.

Underpinning the StaRI reporting standards are the dual strands of describing, on the one hand, the **implementation strategy** and, on the other, the clinical, healthcare, or public health **intervention** being implemented.[17] These strands are represented as two columns in the checklist (see Table 2). The primary focus of implementation science is the implementation strategy [15] (column 1) and the expectation is that this will always be fully completed. The impact of the intervention on the target population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. Whilst all items are worthy of consideration, not all items will be applicable to or feasible in every study; a fully completed StaRI checklist may thus include a number of ‘not applicable’ items.

**Elaboration on individual checklist items**

<b>Item 1. Title</b>
Identification as an implementation study, and description of the methodology in the title and/or keywords
<i>Examples</i>
<b>Titles</b>
Accessibility, clinical effectiveness, and practice costs of providing a telephone option for routine asthma reviews: phase IV controlled implementation study.[18]

---

Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program.[19]

---

### *Explanation*

In addition to specifying the study design used (e.g. cluster RCT, controlled before-and-after study, mixed-methods, economic evaluation etc.), it is important to identify the work explicitly as an implementation study, so that indexers, readers and systematic reviewers can easily identify relevant studies. Both study design and 'implementation study' should be included as key words and in the abstract.

### **Item 2. Abstract**

Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.

### *Example*

---

#### **Abstracts**

---

Background: Attendance for routine asthma reviews is poor. A recent randomised controlled trial found that telephone consultations can cost-effectively and safely enhance asthma review rates...

Design of study: Phase IV controlled before-and-after implementation study.

Setting: A large UK general practice.

Method: Using existing administrative groups, all patients with active asthma (n = 1809) received one of three asthma review services: structured recall with a telephone-option for reviews versus structured recall with face-to-face-only reviews, or usual-care (to assess secular trends). Main outcome measures were: proportion of patients with active asthma reviewed within the previous 15 months... mode of review, enablement, morbidity, and costs to the practice.[18]

---

Background: Good quality evidence has been summarised into guideline recommendations to show that peri-operative fasting times could be considerably shorter than patients currently experience. The objective of this trial was to evaluate the effectiveness of three strategies for the implementation of recommendations about peri-operative fasting.

Methods: A pragmatic cluster randomised trial underpinned by the PARIHS framework was conducted during 2006 to 2009 with a national sample of UK hospitals using time series with mixed methods process evaluation and cost analysis. Hospitals were randomised to one of three interventions: standard dissemination (SD) of a guideline package, SD plus a web-based resource championed by an opinion leader, and SD plus plan-do-study-act (PDSA). The primary outcome was duration of fluid fast prior to induction of anaesthesia. Secondary outcomes included duration of food fast, patients' experiences, and stakeholders' experiences of implementation, including influences. ANOVA was used to test differences over time and interventions.

Results: Nineteen acute NHS hospitals participated. Across timepoints, 3,505 duration of fasting observations were recorded. No significant effect of the interventions was observed for either fluid or food fasting times. The effect size was 0.33 for the web-based intervention compared to SD alone for the change in fluid fasting and was 0.12 for PDSA compared to SD alone. The process evaluation showed different types of impact, including changes to practices, policies, and attitudes. A rich picture of the implementation challenges emerged, including interprofessional tensions and a lack of clarity for decision-making authority and responsibility.[20]

---



Explanation

For clarity of indexing and identification, the abstract should state clearly the study design and identify the work as an implementation study. In line with the concept of dual strands that underpins the StaRI checklist, both the implementation strategy and the evidence-based intervention being implemented should be described. Other important information that should be included are the context, implementation outcomes, resource use and, if appropriate, health intervention outcomes.

Item 3. Introduction (Identify the problem)

Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.

Examples

Identify the problem

In the U.S., a substantial percentage of morbidity and mortality (about 37%) is related to four unhealthy behaviors: tobacco use, unhealthy diet, physical inactivity, and risky alcohol use... Primary care clinicians have many opportunities to assist their patients in modifying unhealthy behaviors; however, they are hampered by inadequate time, training, and delivery systems.[21]

Despite significant morbidity, attendance for routine asthma reviews is poor... Telephone consultations offer alternative access to routine asthma reviews, although a recent UK ruling decreed that the evidence base for this approach in asthma care was 'insufficient'.[18]

Explanation

Identifying and characterising the problem or deficiency that the intervention was designed to address may require data on, for example, the epidemiology of the condition, its impact on individuals or healthcare resources, and evidence of a 'research to practice' gap (e.g. actual performance rates). Characterising the challenge for implementation requires a description of the context in which the intervention will be implemented. This should include a summary of the key factors that might affect successful implementation in terms of the wider context (e.g. governmental policies, major philosophical paradigms influencing decision makers, availability of resources) as well as barriers and enablers within the organisation and at individual professional level.[9]

**Item 4. Introduction (Rationale: implementation strategy and intervention)**

The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).

The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

*Example*

Rationale for the implementation strategy	Rationale for the intervention
Facilitated rapid-cycle quality-improvement techniques (plan–do–study–act cycles [PDSA]) and learning collaboratives are effective in primary care settings, and the two strategies ought to be complementary.[21]	... brief interventions delivered in primary care office settings have affected smoking cessation and alcohol consumption. Although less evidence supports brief interventions for improving diet or increasing exercise, there are reasons for optimism.[21]
The Health Decision Model, which combines decision analysis, behavioral decision theory, and health beliefs, is useful to identify patient characteristics related to treatment adherence and subsequent blood pressure control... Successful implementation generally requires a comprehensive approach, in which barriers and facilitators to change in a specific setting are targeted.[22]	If not properly controlled, elevated blood pressure (BP) can lead to serious patient morbidity and mortality... Inconsistent patient adherence to the prescribed treatment regimen is known to contribute to poor rates of BP control and improving medication adherence has been shown to be effective in improving BP.[22]

*Explanation*

Authors of implementation studies need to explain the rationale both for the choice of implementation strategy and for the validity of the intervention being implemented:

- The implementation strategy will be described in detail in the methods, but it is likely to be appropriate in the introduction to identify the approach used with supporting evidence for the choice of implementation theory/model/framework adopted (see first example: plan–do–study–act cycles [21]) and/or any pilot work or examples from other clinical areas or contexts. It will be important to show how the implementation strategy has been adapted to fit the context.
- The expectation is that there will be (ideally robust) evidence for the intervention (see second example: improving adherence improves BP control which reduces morbidity[22]). It is important that the strength of evidence is made explicit at the outset,[23] especially as sometimes there is pressure to implement an intervention before the evidence base is fully developed (e.g. for political imperatives). This will allow a judgement as to whether it is reasonable to assume that effective implementation will improve health outcomes or whether it is necessary to also assess

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

health outcomes. Effective implementation of some interventions may have such incontrovertible evidence of benefit (e.g. reducing smoking prevalence) that a health outcome may be unnecessary. Even when evidence is strong, the possibility that the impact of an intervention may be attenuated when it is implemented in routine practice needs to be considered.

It is recommended that reporting the methods, outcomes and conclusions related to the implementation strategy precedes the corresponding reporting of the health outcomes of the intervention (because the key question in an implementation study is about the impact of the implementation strategy). However, authors may wish to reverse this in the introduction and establish that the intervention is effective before explaining the approach they took to implementing it. The use of hybrid study designs, which combine features of clinical effectiveness and implementation studies, may affect the relative emphasis that is placed on the implementation and health intervention aspects of trials.[14]

**Item 5. Aims and objectives**  
The aims of the study, differentiating between implementation objectives and any intervention objectives.

*Example*

Aims
The aim of our study is to evaluate the process and effectiveness of supported self-management (SMS) implemented as an integral part of the care for patients with type 2 diabetes mellitus provided by practice nurses. We will simultaneously address the following research questions: 1. What is the uptake of the SMS programme by the practice nurses, and what barriers hamper the implementation of SMS in routine primary care? 2. What is the effectiveness of SMS in terms of daily functioning, emotional health status, social participation, self-management behaviour, and health care use by patients with type 2 diabetes?[24]

*Explanation*

The aims and objectives should distinguish between the aim(s) of the implementation strategy and the aim(s) of the evidence-based intervention that is being implemented, possibly using two specific research questions as in the example.[24] The aim of the intervention may be implicit if there is

already strong evidence to support the health benefits of the intervention (e.g. reducing smoking prevalence).

#### Item 6. Methods: study design

The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons

##### *Example*

##### **Study design**

The trial was designed as an implementation study with a before and after analysis.[25]

Implementation of Perioperative Safety Guidelines is a multicenter study in nine hospitals using an one-way (unidirectional) cross-over cluster trial design ... It is impossible to deliver such a strategy simultaneously to all hospitals because of logistical, practical, and financial reasons. For that reason, a stepped wedge cluster randomized trial design is chosen.[26]

##### *Explanation*

The study design should be identified and the rationale explained. Any important changes to the study protocol should be described (or the absence of changes confirmed).

In contrast to most reporting standards, StaRI is applicable to a broad range of study designs, for example cluster RCTs, controlled clinical trials, interrupted time series, cohort, case study, before and after studies, as well as mixed methods quantitative/qualitative assessments.[2] A hierarchy of study design has been suggested in the context of studies implementing asthma self-management.[4] Reporting standards exist for many of these designs such as cluster RCTs,[27] pragmatic RCTs,[28] observational studies,[29] including use of routine data,[30] non-randomised public health interventions,[31] qualitative studies,[32] as well as templates for describing interventions,[33] and local quality improvement initiatives.[34] The StaRI checklist does not, therefore, include items related to specific design features (e.g. randomisation, blinding, intra-cluster correlation, matching criteria for cohorts, data saturation). Authors are referred to appropriate methodological guidance on reporting these aspects of their study (available from <http://www.equator-network.org>)

#### Item 7. Methods: context

The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).

Examples

Context

The program occurred in three of 14 community-based networks that are part of the statewide Community Care of North Carolina (CCNC) program, an outgrowth of a two-decade effort in North Carolina to better manage the care of Medicaid patients through enhanced patient-centered medical homes. This public-private partnership has five primary components ... developed to mirror the components of the Wagner Chronic Care Model for the organization of primary care. At a statewide level, CCNC is operated by North Carolina Community Care Networks, Inc. (NCCCN), a non-profit, tax-exempt organization that facilitates statewide contracting between the 14 CCNC networks and healthcare payers, including Medicaid and Medicare, and allows the participating regional networks to share information technology and other centralized resources. NCCCN also serves as a centralized resource for quality improvement, reporting, web-based case management system, practice support, and provider and member education.[22]

All Italian citizens are covered by a government health insurance and are registered with a general practitioner. Primary care for diabetes is provided by general practitioners and diabetes outpatient clinics. Patients can choose one of these two ways of accessing the healthcare system, according to their preferences, or they can be referred to diabetes outpatient clinics by their general practitioners. The Italian healthcare system includes more than 700 diabetes outpatient clinics. The SINERGIA model is based on a process of disease monitoring and management that tends to exclude the intervention of the diabetologist in the absence of acute problems. Therefore, diabetologists gain time for patients with more severe diabetes, thus enabling them to provide highly qualified care to those patients.[35]

Delivering a multifactorial intervention in our local setting is challenging. Data from a neighboring province showed marked underuse of proven therapies in subjects with diabetes. Furthermore, there is a shortage of physicians, especially in rural areas, while fee-for-service reimbursement may not favor optimal chronic disease management. Although the local prevalence of diabetes (currently 5.3%) is increasing, the greatest incidence and prevalence are in northern communities, which have the least access to specialists.[36]

Explanation

Successful implementation of evidence into practice is a planned facilitated process involving the interplay between individuals, evidence, and context to promote evidence-informed practice.[37] A rich description of the context is critical to enable readers to assess the external validity of the study,[38] and decide how the study context compares to their situation and if/how the implementation strategy might be transposed, or need adapting.[39] Similarly, the social, political, and economic context influences the ‘entrenched practices and other biases’ that hinder evidence-based de-implementation of unproven practices.[40,41]

The Consolidated Framework for Implementation Research (CIFR) defines 39 constructs that may guide reporting of these contextual dimensions [http://www.cfirguide.org/imp.html]. The constructs are clustered within five domains:[9,42]

- ‘Characteristics of the intervention being implemented’ including strength of evidence,

adaptability, cost

- 'Outer domain' including alignment with patient needs, peer pressure/competition, external policy, political drivers, economic climate, incentives, timescales
- 'Inner domain' including characteristics and culture of the organisation, perceived need for and capacity to change, leadership and resources
- 'Characteristics of individuals' including attitude, self-efficacy, role within the organisation
- 'Process' by which changes are planned and executed within the organisation

Journal word restrictions will dictate how much detail can be included in the text, but authors should highlight all the key contextual barriers and facilitators that are likely to influence their implementation strategy and outcomes. The examples above highlight the policy context promoting patient-centred medical homes,[22] the role of diabetologists that enabled a shift in care,[35] and the shortage of specialists that challenged implementation.[36] Additional information may be provided in an on-line supplement or a separate publication.

#### Item 8. Methods: Targeted sites and populations

The characteristics of the targeted 'site(s)' (e.g. locations/ personnel/ resources etc.) for implementation and any eligibility criteria.

The population targeted by the intervention and any eligibility criteria.

#### Example

Sites and population targeted by the implementation strategy	Sites and population targeted by the intervention
This study comprises nine hospitals in the Netherlands: two academic, four tertiary teaching, and three regional hospitals, with 200 to up to more than 1,300 beds each. ...we believe these hospitals represent the practice of Dutch hospital care.[26]	The study focuses on patients undergoing elective abdominal or vascular surgery with a mortality risk $\geq$ 1%. These surgeries are selected because of the estimated higher risk of complications and hospital mortality...[26]
The study will be implemented in public health facilities in Central and Eastern provinces in Kenya and in three regions in Swaziland... The two criteria for selecting intervention facility selection were: i) good performance in the previous study and ii) high throughput of family planning clients ( $\geq$ 100/month).[43]	All clients entering the facility for MCH [maternal and child health] services over the five-day period will be asked to participate...[43]

Explanation

Recruitment is considered at two levels:

1. The groups/organisations/locations/providers that were targeted as potential ‘sites’ for the implementation. Although there may be some overlap with the description of the organisational context (item 7), this is a more specific item related to recruitment strategy including sampling and eligibility criteria. In the second example, the context might describe public health facilities in Kenya and Swaziland; the extract refers to the study-specific requirements of good performance in previous studies and high throughput of family planning clients.[43] Note that this is a description of *targeted* sites; a description of *participating* sites will be in the results.
2. The population targeted by the intervention being implemented including any eligibility criteria. In a clinical context, this might be people with a specific condition (such as requiring abdominal or vascular surgery in the first example),[26] registered with a participating site, and there may be criteria (such as high risk of mortality [26]) that define the population for whom the intervention is appropriate.

Item 9. Methods: Description	
A description of the implementation strategy.	A description of the intervention
Example	
Description of the implementation strategy	Description of the intervention
Implementation planning for this study began with the construction of multiple stakeholder partnerships within the VA PC-MHI program.... [and] was informed by the Promoting Action on Research Implementation in Health Services (PARiHS) framework.... Based on stakeholder feedback and project-team experiences, the implementation strategy for this trial was developed to include three separate but interrelated interventions— online clinician training, clinician audit and feedback, and internal and external facilitation... .. emphasis has been placed on understanding stakeholder perspectives, using formative and process evaluations such that the implementation interventions could be modified as needed during the trial.[44]	The ACCESS intervention is a manualized brief CBT [Cognitive Behavioural Therapy] protocol that provides a flexible, patient-centered approach to increase patient engagement and adherence, while addressing both the mental and physical health needs of veterans [chronic obstructive pulmonary disease or heart failure]. ACCESS consists of six weekly treatment sessions and two brief (10- to 15-minute) telephone “booster” sessions within a four month time frame. Participants are asked to attend the first session in person and can participate in subsequent sessions by telephone or in person.[44] Detailed descriptive information about the content and processes of the ACCESS intervention can be found elsewhere.[45]
Sites not initially responding to REP [Replicating Effective Programs] (defined as <50% patients	The EBP to be implemented is Life Goals (LG) for patients with mood disorders across 80 community-

receiving $\geq 3$ EBP [evidence-based practice] sessions) will be randomized to receive additional support from an EF or both EF/IF [Internal Facilitator]. Additionally, sites randomized to EF and still not responsive will be randomized to continue with EF alone or to receive EF/IF. The EF provides technical expertise in adapting [Life Goals] in routine practice, whereas the on-site IF has direct reporting relationships to site leadership to support LG use.[19]	based outpatient clinics... LG is a psychosocial intervention for mood disorders delivered in six individual or group sessions, which includes 10 components: self-management sessions, values, collaborative care, self-monitoring, symptom profile, triggers, cost/benefit analysis of responses, life goals, care management, and provider decision support. Based on social cognitive theory, LG encourages active discussions focused on individuals' personal goals that are aligned with healthy behavior change and symptom management strategies.[19]
--	--

### Explanation

Descriptions of implementation strategies and complex interventions are criticised as being inconsistently labelled, poorly described, rarely justified, not easy to understand.[15,46,47] and not sufficiently detailed that the intervention could be replicated.[48]

There needs to be a description of both the implementation strategy and the intervention being implemented (see also item 12 with a description of 'logic pathways').

1. Implementation strategies are the 'bundle' of techniques used to enhance the adoption, integration into routine practice, and sustainability of a clinical programme or practice.[14] The Cochrane Effective Practice and Organisation of Care (EPOC) Review Group, considers strategies in the categories of professional, financial, organisational and regulatory.[49] Others have identified 73 potential implementation techniques from which relevant components may be selected.[50] A framework such as that described by Proctor *et al* would enable consistent comprehensive reporting:[15]
  - **Actors:** The key players (e.g., administrators, payers, providers, patients/consumers, advocates) who enact the strategy – or enable the strategy to be enacted. The investigator's role should be explicit (e.g. a public health strategy over which they have no control vs. an implementation process which they are driving).
  - **Action:** The specific activities, steps, or processes that constitute the implementation strategy, and how and when these may interact.



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- Action target: Strategies may be targeted at specific barriers, enablers, characteristics of the context, processes and other factors influencing the adoption of the intervention. The personnel, organisation, or activity targeted by the implementation strategy should be described.
- Temporality: The steps, sequence of actions, and timeframe over which the strategy is to be enacted
- Dose: Frequency, duration and intensity of the actions of implementation strategy.
- Implementation outcome(s) likely to be affected by the strategy: Outcomes are defined in Item 11; but it may be helpful to signpost these at this stage to ensure that chosen outcomes link explicitly to the implementation strategy and the proposed mechanism of action.
- Theoretical, empirical, and/or pragmatic justification for the choice of implementation strategies: These may have been identified in the introduction (Item 4), but reference to theoretical models, mapping determinants of practice to effective implementation techniques, and any pilot work are likely to be appropriate in the methods.

Word counts will restrict the description possible within the text, but authors should consider writing a more detailed description, for example as a supplementary on-line file. Standards for reporting behavioural change interventions (WIDER) recommend providing access to a manual.[51] Some have called for an ‘intervention bank’ in which manuals, videos, descriptions of implementation strategies and interventions, and other related materials can be stored.[52] One practical option is to tabulate this information (see Table 3). Alternatively, diagrams or schema may be used to represent the interacting components of an implementation strategy. Graphical representations,[53] or ‘cascade diagrams’ have been devised depicting complex interventions,[54] and may have potential in describing multilevel implementation studies. Figure 1 is an exemplar utilising a timeline.[18]

2. The intervention that is being implemented also needs to be described, and any developmental work undertaken to adapt the intervention for implementation cited.[55] TIDieR highlights the

‘who, why, what, where, when and how much’ of describing an intervention.[33] Designed to standardise reporting of the development of complex interventions, the CReDECI checklist [56] may aid description of developing and piloting implementation of an intervention.

Different sites participating in the implementation study are likely to adapt further the intervention to suit their specific context and authors should consider distinguishing between core components of the intervention (to which fidelity is expected) and elements where adaptation is allowed or even encouraged (see also item 22). A box with details of the intervention may conveniently distinguish it from the description of the implementation strategy.[56]

In study designs that include a comparator group, the description of ‘usual care’ provided to the non-intervention groups should be sufficiently detailed to enable a reader to judge comparability with their practice and thus the likely impact of the intervention if implemented in their own setting.

**Item 10. Methods (Sub-groups)**

Any sub-groups recruited for additional research tasks, and/or nested studies are described

*Example***Sub-groups**

Observations of client-provider interactions: 18 consecutively sampled new family planning/HIV clients and 18 revisit clients ... will be observed. For the post-natal clinic/HIV model ... 24 consecutively sampled postpartum women (within 48 hours of birth, between one to two weeks and around six weeks postpartum) per study facility [will be recruited].[43]

Researchers posted the following validated questionnaires, with two reminders, to patients with active asthma in the three groups at the end of the study year (excluding children aged less than 12 years, as the questionnaires are not validated for this age group). The only exclusion criteria were a predominant diagnosis of chronic obstructive pulmonary disease, inability to complete the questionnaire (for example, because of severe dementia), and patients excluded by their GP for significant medical or social reasons.[18]

*Explanation*

Typically in implementation studies, the people targeted by the intervention (e.g. patients with a condition registered with a practice or healthcare organisation; population targeted by a public health initiative) will not have consented to the research. Some studies may recruit a sub-group of patients to undertake specific research activities. For example, a proportion of consultations may be

observed (see the first example[43]), a random sample of patients provided with a new service may be asked to complete questionnaires (see the second example[18]) or a purposive sample of stakeholders may be recruited for a qualitative study. The recruitment process for these sub-groups should be clearly described.

**Item 11. Methods: Outcomes**

Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets.	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets.
---	--

*Example*

Outcomes of the implementation strategy	Outcomes of the intervention
The primary outcome measure is guideline adherence according to the perioperative Patient Safety Indicators as defined in the national indicator set. This set comprises nine indicators on the processes and structures of care.[26]	Secondary (patient) outcomes are in-hospital complications (with particular attention to postoperative wound infections) and hospital mortality, as well as length of hospital stay, unscheduled transfer to the intensive care unit, non-elective hospital readmission, and unplanned reoperation...[26]
Implementation outcomes To assess brief cognitive behavioral therapy (CBT) adoption and fidelity, as measured by: a) brief CBT patient engagement (one or more sessions) and adherence (four or more sessions) b) Department of Veterans Affairs Primary Care-Mental Health Integration [VA PC-MHI] clinician brief CBT adherence and competency ratings as evaluated by expert audio session reviews.[44]	Effectiveness outcomes: To determine whether a brief CBT treatment group as provided by VA PC-MHI clinicians is superior to a usual-care control group at post treatment and 8- and 12-month follow-ups, as measured by: a) depression and anxiety scores (Patient Health Questionnaire-9 and Beck Anxiety Inventory) b) cardiopulmonary disease outcomes (Chronic Respiratory Questionnaire and Kansas City Cardiomyopathy Questionnaire).[44]

*Explanation*

Figure 2 illustrates the outcomes relevant to implementation science and the StaRI checklist items to which they relate. This schema borrows from the conceptual models and taxonomy of outcomes described by Proctor et al,[16,57,58] but also highlights the dual strands suggested by the StaRI guideline as underpinning reporting implementation intervention studies. The outcomes are mapped to the checklist items in which they are described or reported. The outcomes related to the implementation strategy should be distinguished from outcomes of the intervention:

1. Implementation is the main objective of implementation studies and the primary implementation outcome takes priority.
2. Impact on the primary health outcome is the ultimate aim of implementing the intervention and is therefore important, though it may not always be measured in an implementation study if the underpinning evidence is sufficiently robust (e.g. bans to restrict exposure to second-hand smoke[59]).

All outcomes should be clearly defined, including the time point at which they are measured in relation to delivery of the implementation strategy, to enable interpretation of findings in the context of an evolving process of adoption of the intervention within organisations and also inform sustainability.

Not all implementation studies will designate a 'primary outcome', but this is of sufficient importance in the context of experimental designs that the terminology has been retained (see Table 2 for alternative terms). This also serves to distinguish implementation outcomes on which a study is powered from the data collected during a process evaluation (see item 12). Feasibility studies may focus on process rather than primary implementation or health outcomes.

The provenance of data is of particular importance in implementation studies in which participants may not be recruited to the research. For example, routine data are typically collected for purposes other than research and the intended use (clinical records, insurance claims, referral patterns, workload monitoring) will influence what and how data are recorded. A description should be provided of the provenance of the data (data source/purpose and process of collection/data completeness) and validity of coding.[30]

It is good practice to define the minimum change that would be considered as representing implementation success (e.g. 70% participation in the intervention) and justify that choice of level.

**Item 12. Methods: Process evaluation**

Process evaluation objectives and outcomes related back to the ‘logic pathway’.

*Example*

**Process evaluation**

The outcomes reported in this paper include adoption, implementation, and maintenance from the Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) Model

Adoption was defined as the percentage of clinicians invited to participate who completed training and implemented recommended changes.

Implementation [of the intervention] was determined by how well the practices were able, during each 6-month cycle, to fully incorporate screening and very brief and brief interventions for each behavior into their processes of care, based on information obtained from the chart audits.

Maintenance was determined by the degree to which practices continued to screen for and provide interventions while working on the other behaviors.[21]

... In this framework (Hulscher et al.[60]), attention is paid to features of the target group, features of the implementers, and the frequency and intensity of intervention activities. Based on this framework we describe the features of the intervention as performed in detail. The process evaluation will furthermore be based on a questionnaire for the contact persons and a questionnaire for the health-care providers to measure their experience with the implementation strategy. ."[26]

*Explanation*

A process evaluation (or formative evaluation) is used to describe the implementation strategy as delivered, and to assess and explore stakeholder experience of the process of implementation and/or target population experiences of receiving the intervention.[60-62] A process evaluation should be based on an explicit hypothesis (e.g. ‘logic pathway’; see Table 2 for alternative terminology) that spans both the mechanism of action of the implementation strategy and the mechanism by which the intervention is expected to improve healthcare. Process data should be related to the hypothesised mechanisms. This implies that data may need to be collected at multiple time points to capture an evolving process, and the relationship between the researcher undertaking the process evaluation and the implementation process (e.g. whether interim results are fed back to facilitate adaptation) should be described.[61,62] Context (see item 7) may be reported as a component of the process evaluation.

For each process evaluation outcome:

- Describe the variables, measures, data sources and data collection methods and frequency, and the analytic approaches employed. Describe who collected data, and the relevance to their role. For example, nurses providing telephone or face-to-face asthma reviews were asked to record duration of consultations,[18] which may have led to inaccuracies either due to the impracticality of accurate data collection during clinical work and/or bias due to perceived implications for their workload. The provenance of routine data should be described. (see Item 12)
- Describe methods for assessing fidelity to (and adaptation of) the implementation strategy and to the intervention, sustainability and learning effects (see also Item 22). Iterative changes as a result of on-going feedback should be described.
- Describe checks employed to assess quality of quantitative and/or qualitative data and analysis. For example, nurses' assessment of duration of consultations could be checked against appointment schedules.[18]

Frameworks such as RE-AIM (Reach, Effectiveness, Adoption, Implementation, & Maintenance),[63] diffusion of innovation,[64] routinisation,[65] NPT (Normalization Process Theory),[66] Framework for process evaluation of cluster-randomised controlled trials (RCT)[67] or Stages of Implementation Completion,[68] **Theoretical Domains Framework [69]** may be useful in developing, analysing and reporting process evaluations.

#### **Item 13. Methods: Economic evaluation**

Methods for resource use, costs, economic outcomes and analysis for the implementation strategy

Methods for resource use, costs, economic outcomes and analysis for the intervention

#### *Example*

<b>Economic evaluation of the implementation strategy</b>	<b>Economic evaluation of the intervention</b>
Cost analysis of developing and implementing the three interventions from a national perspective (cost	... from the perspective of a single trust (cost of all activity and resource used by trust employees in

of rolling out a particular intervention across the NHS)...[20]	implementation)[20]
Financial data were obtained for the costs of setting up and running the Improving Access to Psychological Therapies (IAPT) service for the 2 years of the study, including training, equipment, facilities and overheads, to provide estimates of the costs associated with IAPT. Set-up costs were a small proportion of total costs (less than 10%) and these were therefore apportioned to this 2-year period rather than the lifetime of the service.[70]	The service recorded contact ... time in minutes for each service user and this was used to calculate total contact time over the 2 years, which was combined with total cost data to generate an average cost per minute for the IAPT service... All health and social care services [were] valued using national unit costs. A broader perspective of costs was taken by assessing productivity impact, which we valued using the lost number of days from work using a human capital approach.[70]

*Explanation*

Economic evaluation can inform future implementation and commissioning decisions. Reporting should adhere to existing guidelines relevant to the study design (for example: the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force guidelines for economic evaluation (including model-based economic evaluation)[71] and budget impact analysis,[72] and guidance on social return on investment approaches[73]). This may require an on-line supplement or a separate publication.

An additional requirement in reporting implementation research is to relate economic information to the implementation strategy or the intervention that is being implemented. If possible, reporting should distinguish between the two, with the practicality of doing so ideally having been considered at design stage. A budget impact analysis estimates changes in the expenditure of a healthcare system after adoption of a new intervention, and will be of particular interest to those who plan healthcare budgets.[72]

Reporting should be transparent and cover the following aspects of the evaluation, as relevant:

- Target/eligible population, health system, setting, location and comparator(s).
- Perspective (i.e. which resources and costs are being considered) using an equivalent approach for intervention and comparator scenarios, with additional and separate estimates specifically related to the implementation strategy and intervention.

- Time horizon of the evaluation and (if relevant) the discount rate used.
- Methods and sources used to derive resource use and cost estimates.
- Currency, price date and any conversions.
- Outcome/effectiveness measure(s).
- Statistical approaches for analysis of resource use, costs and outcomes, including handling of joint distributions between these parameters, handling of missing data and any specific considerations e.g. cluster randomisation.[74]
- For models and budget impact analyses, the choice of model/framework, its structure (with graphical representation) and methods for checking consistency and validity.
- For approaches that report composite cost and outcome metrics (e.g. incremental cost-effectiveness ratio or probability of cost-effectiveness against a given willingness-to-pay threshold), the outcome should be clearly specified and justified (particularly if it is not the same as the primary outcome for the related effectiveness evaluation).
- Assumptions made, and any planned sensitivity/scenario analyses to explore the impact of such assumptions.

#### Item 14. Methods: sample size

Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)

##### *Example*

##### **Sample size**

Assuming an alpha of 0.05 and a beta of 0.90, an improvement in perceived daily functioning (defined as a score less than or equal to 4 on the Daily Functioning Thermometer, our primary outcome) at T12 occurring in 20% of the patients in the intervention group versus 5% of those in the control group requires at least a net number of 116 patients per arm (N= 232; 5 patients per practice nurse). It will be necessary to take account of a possible dependence between observations on patients of the same practice nurse (PN). The intra-class correlation coefficient (ICC) is assumed to be 0.04, a median value for cluster-RCTs in the primary care setting [33]. Assuming a 30% loss to follow-up we need to recruit at least 331 patients (8 per PN). Since participation in the screening procedure will not necessarily mean that patients also give informed consent for the effect evaluation, 10 consecutive patients for each PN will be invited to participate in the effect evaluation (N= 460).[24]

##### *Explanation*



It is important to recruit sufficient participants to be able to address the study’s implementation objectives; the rationale for the number of sites and/or people recruited to the study needs to be justified. In a trial (e.g. a cluster RCT), this will be based on a sample size calculation using the primary implementation outcome. If health outcomes are also being assessed consideration may need to be given to the sample size for the primary health outcome. Design-specific advice on reporting sample size calculations can be found in relevant reporting standards.[27-29,31,75] In studies using qualitative methodology, data saturation may inform the final sample size. Budgetary constraints and other pragmatic considerations may also be relevant (such as evaluating an initiative in which size is already determined; in the second example the sample was ‘all active asthmatics’ in the practice.[18]).

<b>Item 15. Methods: analysis</b> Methods of analysis (with reasons for that choice)
<i>Example</i>
<b>Analysis</b>
<i>Numerical data</i> Analysis was conducted at the cluster level for each Trust... At each time-point, the differences in mean fasting times between the three intervention groups were compared using analysis of variance (ANOVA). A repeated measure ANOVA across the time-point means for all trusts, within each intervention group, was conducted. The trend coefficient was not significantly different to zero: there was no evidence of trend over time pre- or post-intervention therefore data were combined across timepoints (1 to 4 and 5 to 8) and simple pre- and post-interventions comparisons were conducted using t-tests. The significance level used for all tests was 5%. The effect size was calculated for each of the web-based and PDSA interventions compared to standard deviation for change in fluid fasting time between pre- and post-intervention..... Patient experience questionnaires were analysed in SPSS using descriptive statistics, chi squared tests were used to compare characteristics pre- and postintervention. .... Descriptive and inferential statistics were conducted (on learning organisational data).
<i>Qualitative data</i> Audio-recorded individual and focus group interviews were transcribed in full. Data were analysed within data set and managed in N*DIST 5 (pre-intervention) and NVIVO 7 (post-intervention). A combined inductive and deductive thematic analysis process was used .....
<i>Synthesis</i> The theoretical framework [developed for this study is based on the Promoting Action on Research Implementation in Health Services (PARIHS) framework guided the integration of findings across data sets.[20]

*Explanation*

Design-specific advice on reporting analysis can be found in relevant standards.[27-29,31,32,75].

Consideration needs to be given to the analysis of primary implementation outcomes and then (if measured) to any health outcomes.

In mixed methods studies, clarity is needed about how different data types (numeric, qualitative) will be managed and analysed.[76] The synthesis of qualitative and quantitative data will be guided by the study's question(s) or objective(s), and by its overarching theoretical framework or theory. Reporting should both describe *and* explain implementation processes (e.g. delivery of intervention, facilitators, barriers), contexts (e.g. characteristics and influence of) and impacts.

#### Item 16. Methods: Sub-group analyses

Any *a priori* sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks

##### *Example*

##### **Sub-groups**

Planned subgroup analyses focus on subgroups of young women. Age is a core issue in gender violence and HIV incidence. ... A further subgroup analysis will examine the effect of the presence of other programmes for HIV prevention, youth empowerment and reduction of gender violence active in the clusters, with this information collected at the time of the impact survey.[77]

##### *Explanation*

Sub-groups should be specified *a priori* and the method of subgroup analysis clearly specified.

Further detail on reporting analysis of data from sub-groups is available in design-specific reporting standards.[27-29,31,75]

#### Item 17. Results: Populations

Proportion recruited and characteristics of the recipient population for the implementation strategy.

Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention

##### *Example*

##### **Characteristics of recipients of the implementation strategy**

Six practices were classed as rural, seven as urban.  
Practice list size ranged from 2,300 to 12,500

##### **Characteristics of recipients of the intervention**

4,434 adult (age range 18 to 55 years) patients with an asthma diagnosis made more than 12 months

(median= 7,500, IQR 5,250-10,250). Four urban and three rural practices were randomly assigned to the intervention group.[78]	previously were identified .... A total of 1572 patients, who had received repeat prescriptions for $\beta$ 2-agonists in the previous 12 months, were defined as active asthma patients. Of these, 667 (42%) were considered to have poorly controlled asthma ...[78]
Forty-three practices were randomized: 22 to the intervention group and 21 to control. Massachusetts practices were a mix of hospital clinics, independent community health centers, and private practices. In Michigan, all sites were a part of the Henry Ford Health System; 1 was hospital-based. ...There were no significant differences in practice characteristics between intervention and comparison groups.[79]	The 43 practices identified a total of 13 878 pediatric patients with asthma who may have been eligible for this study. ... Unexpectedly, at baseline, 53% of the children in the intervention group had a written asthma management plan, compared with 37% of the children in the control group (P0.001). The groups were not different at baseline with respect to any other measure.[79]

Explanation

As in cluster RCTs, the populations need to be considered at two levels:

1. Characteristics of the participating sites (e.g. demography of a practice/clinic) and the personnel (professional training, staff skills) who were recipients of the implementation strategy, and control groups (if applicable), and their representativeness compared to the sites targeted. Note that characteristics of targeted sites are reported in the methods (Item 8)
2. Characteristics of recipients of the health intervention. As these individuals will often not have consented to participate in the research, information is likely to be limited to routine anonymous data.

At each level reach, (the proportion of eligible population who participated and their characteristics) needs to be reported. A diagram illustrating the flow of targeted/participating sites, professionals and patients may be helpful, potentially adapted from CONSORT standards for cluster RCTs.[27] Published examples of diagrams include a cohort study;[79] a controlled implementation study;[18] and a before and after study.[79]

Item 18. Results: Outcomes	
Primary and other outcome(s) of the implementation strategy.	Primary and other outcome(s) of the Intervention (if assessed)

Example

Primary (and other) outcomes of the implementation strategy	Primary (and other) outcomes of the intervention (if assessed)
The Assessment of Chronic Illness Care	Changes in measures of disease control were more

measurements, obtained at the beginning, midpoint and end of the initiatives, provide evidence of the progressive implementation of the components of the CCM [Chronic Care Model]. These results are described using a spider diagram.[81]	modest.... Nevertheless, tracking aggregate data by means of Shewhart p charts showed special cause variation reflecting improvement in blood pressure and [cholesterol] control in the late stages of the California Collaborative. Significant changes were not seen in HbA1c levels.[81]
There were 4,550 individuals who met inclusion criteria of which 558 individuals were contacted and received at least a phone contact... On average, individuals received 4.5 phone contacts over the 6-month intervention period.[22]	During the 90 days prior to the first intervention encounter (index date), 35% of patients were >80% adherent to hypertension medication. By the period of 90–179 days following the first encounter, 54% had >80% adherence for hypertension medication.[22]

### Explanation

We suggest that the primary and other outcomes of the implementation strategy are presented before the impact of the intervention on primary and other health outcomes (if measured).

Authors are referred to design-specific standards for detailed advice on reporting outcomes.[27-31]

## Item 19. Results: Process evaluation

Process data related to the implementation strategy mapped to the 'logic pathway'.

### Example

#### Process data

The Park County Diabetes Project made a number of **changes in the delivery of diabetes care and patient education**. These included establishing and maintaining patient registries; nurses conducting mail and telephone outreach to patients in need of services; mailing personalized patient education materials regarding the ABCs of diabetes; and providing ongoing continuing education workshops for the health care team. The team redesigned the education curriculum ..., provided group education sessions in community settings, and offered classes regardless of the person's ability to pay. The diabetes nurse in each clinic also provided one-on-one diabetes education.

In October 2000, there were 320 patients with diagnosed diabetes receiving care at these clinics, and that number increased to 392 by February 2003. Among (participating) patients, the proportion receiving an annual foot examination, influenza immunization, and a pneumococcal immunization increased significantly from baseline to follow-up. [82]

We identified three sub-themes that clearly distinguished low from high implementation facilities. First, the high quality of working relationships across service and professional ... boundaries was apparent in the high implementation facilities... ... The MOVE! teams at the two high implementation and transition facilities met regularly... ... In the low implementation facilities, communications were poor between staff involved with MOVE! and they did much of their communication through email, if at all.[83]

### Explanation

Process evaluation should be related to the logic pathway, capturing the impact of **the implementation strategy on intermediate/process outcomes on the pathway**. It will be important to **capture the involvement of the stakeholders in the process of design and implementation (e.g. in the**

first example where the team redesigned the existing education curriculum). Data of importance to the main ‘outcome’ are likely to include uptake of and attrition from training, implementation tasks etc. with explanatory insights from qualitative evaluation (e.g. in the second example). If health outcomes are reported, uptake of the intervention by the eligible population will be crucial (as in the first example). Additional papers may be necessary to report all aspects of process data, and to ensure that some publications directly focus on issues of importance to specific groups (e.g. policy-makers, healthcare managers).[61]

Item 20. Results: economic evaluation	
Resource use, costs, economic outcomes and analysis for the implementation strategy	Resource use, costs, economic outcomes and analysis for the intervention

Example

Health economic outcomes (Implementation strategy)	Health economic outcomes (Intervention)
Estimated total up-front investment for this Coordinated-Transitional Care (C-TraC) pilot was \$300 per person enrolled, which includes all staff, administrative, and implementation costs.[84]	... given the observed decrease in re-hospitalizations of 5.8% versus the comparison group, it is estimated that the C-TraC program avoided 361.6 days in acute care over the first 16 months, leading to an estimated gross savings of \$1,202,420. After accounting for all program costs, this led to estimated net savings of \$826,337 overall or \$663 per person enrolled over the first 16 months of the program...[84]
In the base-case analysis, the difference in costs between intervention and control group was £327, and the difference in QALYs was 0.027, which generated an ICER point estimate of £12 111 per QALY gained. The probability of the intervention being cost effective was 89% at the NICE threshold of £30 000 per QALY.[85]	

Explanation

Reporting of economic results should adhere to existing relevant guidelines.[71,72] It should be clear whether the economic results relate to the implementation strategy, the intervention that is being implemented, or both. Reporting should be transparent and cover the following aspects of the evaluation:

- Full description of study parameters, including representation of variation, with separate reporting of resource use and costs. For models and budget impact analyses, all input parameters should be reported separately.
- For composite cost and outcome metrics (e.g. an incremental cost-effectiveness ratio (ICER) or a probability of cost-effectiveness against a given willingness-to-pay threshold), individual costs and outcomes should additionally be reported separately.
- Separate reporting of any sensitivity analyses.
- Provision of budget impact calculators or simulation model programmes may be valued by healthcare decision-makers, and should be developed following specific guidance.[72]

#### Item 21. Results: sub-groups

Representativeness and outcomes of subgroups including those recruited to specific research tasks

##### Example

##### Representativeness of sub-group

236 (37% of the 629 patients with poorly-controlled asthma) patients consented to provide questionnaire data. One hundred and six (45%) patients were from control practices, and 130 (55.1%) were from intervention practices. Patients with asthma who consented to provide baseline questionnaire data were significantly older, more likely to be female and more affluent than non-consenters. They had significantly fewer  $\beta_2$  agonists inhaler or courses of oral steroids prescribed in the 12 months pre-study than non-consenters.

One hundred and seventy-seven questionnaires were returned at follow-up out of a possible 236 (75%). Of these, 78/106 (74%) were returned by control practice patients and 99/130 (76%) from intervention practice patients.[78]

##### Explanation

Sub-group analyses should be distinguished from outcomes from whole populations (e.g. by reporting in a separate table) and their representativeness compared to the whole eligible population.

#### Item 22. Results: Fidelity and adaptation

Fidelity to the implementation strategy as planned and adaptation to suit context and preferences.

Fidelity to delivering the core components of intervention (where measured).

##### Example

##### Fidelity and adaptation to the implementation strategy

##### Fidelity and adaptation to the intervention

Although practices were expected to participate fully in the intervention, actual participation varied

considerably. Attendance at the 3 learning sessions declined progressively from the first to the third in both states (eg, 34 participants at the first session in Boston; 24 at the third). On average, only 42% of the practices submitted performance data ... with fewer practices reporting in the later months of the intervention.[79]		
At AD [academic detailing] visit 3... ... 46% of the PDAs [personal digital assistants] indicated that the provider had discontinued use between visits 2 and 3. ...Several providers reported that, once they adopted electronic medical record systems, they were less inclined to enter data into the PDA (to avoid having to interface with 2 different computers).[86]		[Intervention: adherence to National Cholesterol Education Program clinical practice guidelines] Appropriate management of lipid levels decreased slightly (73.4% to 72.3%) in intervention practices and more markedly (79.7% to 68.9%) in control practices. The net change in appropriate management favored the intervention (+9.7%; 95% confidence interval.[86]

Explanation

Fidelity may be considered at two levels: implementation fidelity and intervention fidelity. Implementation fidelity refers to the degree of adherence to the described implementation strategy. Intervention fidelity is the degree to which an intervention is implemented as prescribed in the original protocol. Both the implementation strategy and the intervention, however, may need to be adapted if they are to fit within the routines of local practice.[86] Adaptation is the degree to which the strategy and intervention are modified by users during implementation to suit the local needs.[26] Insufficient fidelity to the ‘active ingredients’ of an intervention dilutes effectiveness,[88] whereas insufficient adaptation stifles tailoring potentially diluting effective implementation.[86] An approach to reporting these apparently contradictory concepts is to define the core components of an intervention to which fidelity is expected, and those aspects which may be adapted by local sites to aid implementation.[59,87] Distinction may be made between an active process of innovative adaptation that facilitates implementation, passive ‘drift’ in which tasks are allowed to lapse,[88] and active subversion which blocks implementation.[90]

Fidelity should be reported:

1. To the core components of the implementation strategy and any adaptations made by participating sites. A systematic meta-review of the literature on fidelity measures described four aspects of fidelity required for a comprehensive assessment (design, training, monitoring of intervention delivery, and intervention receipt).[91]

2. To delivery of the core components of the intervention (or at least considered if not measured) and any adaptations made.

**Item 23. Results: context**

Contextual changes (if any) which may have affected the outcomes

*Example***Contextual changes**

The present study coincided with the introduction of the UK General Medical Services contract in January 2004 which rewards practices who achieve clinical standards, including a target of 70% for the annual review of people with 'active' asthma. The impact of this was seen in the usual-care group which increased the review rate by 14% without a structured recall service.[18]

*Explanation*

There should be a description of any important contextual changes (or not) occurring during the study that may have affected the impact of the implementation strategy – for example, policy incentives, parallel programmes, changes in personnel, media publicity. The CIFR constructs (see item 7) is a useful framework for describing context, and a timeline (see Item 9) may be a convenient way to illustrate potential impact of contextual changes.

**Item 24. Results: harms**

All important harms or unintended effects in each group.

*Example***Reporting of harms**

[In the context of a computerised decision support to improve prescribing in pregnancy] Two factors contributed to alerts being based on incorrect patient pregnancy status: either the updated diagnosis had not been coded into administrative data at all or transfer of the updated coded diagnosis information from hospital administrative data to health plan administrative data was delayed.[92]

*Explanation*

Adverse or unintended consequences of implementation studies are often under-reported.[93-95] Any important harms or unintended effects should be reported, quantified (e.g. on health outcomes, organisational efficiency or user satisfaction) and possible reasons identified (e.g. flaws in the intervention, context challenging implementation),[91]).



**Item 25: Discussion: summary**

Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications.

*Example*

**Summary findings**

The participating practices adopted most elements of the CCM [Chronic Care Model], including development of inter-professional teams, delegation of provision of care by appropriate team members, implementation of patient self-management strategies, group visits, proactive patient management—anticipating the needs of patients as opposed to providing reactive management—and use of an information system to track individual patient measures. In addition, resident training programs successfully incorporated educational strategies for learning the elements of evidence-based chronic illness care.[81]

*Explanation*

The structure of the discussion will follow the style of the journal, but ideally should include summary of findings, strengths and limitations, comparisons with other studies, implications (see Item 26) and conclusions.[96]

**Item 26. Discussion: Implications**

Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability).

Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability).

*Example*

Implications related to the implementation strategy	Implications related to the intervention
These initiatives suggest that both the practice redesign required for implementation of the CCM [Chronic Care Model] and linked educational strategies are achievable in resident continuity practices.... Durable implementation of the CCM in resident practices necessitates substantial commitment from local institutional, clinical and academic leadership.[81]	...the modest improvement in clinical outcomes observed in these practices in comparison with initiatives from single site initiatives reported in the literature suggests that effective care of patients with chronic illness may require prolonged continuity of care that poses a challenge in many resident practices, even in those committed to implementation of the CCM.[81]
Including a telephone option as part of a review service for people with asthma is a practical and cost-effective strategy for enhancing access... These findings have direct clinical implications and also policy implications for those setting standards for the Quality and Outcomes Framework of the UK GMS [General Medical Services] contract.[18]	

*Explanation*

The authors should reflect on:

1. The implications of the success (or otherwise) of the implementation strategy, both for research and practice.
2. The health benefits (or otherwise) of implementing the intervention.

Target might include citizens, practitioners interested in the health intervention, researchers interested in the conceptual and theoretical perspective, managers and clinical leaders interested in implementing the intervention, and those interested in the broader policy implications. A key point for consideration will be 'sustainability' (the extent to which the intervention can continue to deliver its intended benefits over an extended period of time after any support has terminated) and how policy could be modified to support on-going implementation.

Scalability, generalisability, applicability and transferability of the implementation strategy may need to be discussed.

**Item 27. General**

Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest.

*Explanation*

Ethical considerations, regulatory approvals, funding and conflicts of interest (including commercial interests, involvement of the owner of a product in the implementation or evaluation) should be reported. Registration of trials is a requirement, and increasingly recommended for other study designs.[29,76] Whilst not yet routine practice in implementation studies, authors may find it useful to be able to refer to a published protocol (for example [19,26,43,77]). The detailed descriptions required comprehensively to describe context, implementation strategies and the intervention will be challenging within the word count of a journal and a published protocol may provide further detail.

**Conclusions**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

The StaRI standards are registered with the EQUATOR Network [<http://www.equator-network.org>] and the checklist is available from BMJ.com. We invite editors of journals publishing interventional implementation studies to consider requiring submission of a StaRI checklist, and authors reporting such studies to adopt the checklist. In the future we would like to work with authors as they apply the checklist to their papers, ‘road testing’ the standards and enabling iterative development.

We are particularly interested in whether the concept of the dual strands (implementation strategy/intervention) resonates with authors and readers of implementation studies. Is it practical to expect authors to consult other methodological checklists for reporting design-specific aspects of their study? We look forward to learning about innovative solutions to providing adequate descriptions of context, implementation strategies and interventions that accommodate the requirements of journals, needs of authors as well as preferences of readers.

Previously published statements have been instrumental in improving reporting standards,[10] and our hope is that StaRI will achieve a similar improvement in the reporting of implementation strategies that will facilitate translation of effective interventions into routine practice.

**Competing interests:**

All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: research grants from Chief Scientist Office (HP), Asthma UK (AS, HP, ST), Farr Institute (AS), NIHR HS&DR (HP, ST), NIHR CLAHRC (ST) for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; CC is Deputy Editor-in-Chief for Academic Emergency Medicine and on the editorial boards for the Journal of the American Geriatrics Society and Annals of Internal Medicine's ACP Journal Club and serves as paid faculty for Emergency Medical Abstracts, JR-M is Director of the NIHR HS&DR Programme, no other relationships or activities that could appear to have influenced the submitted work.

**Authors' contributions:** HP initiated the idea for the study and with ST led the development of the protocol, securing of funding, study administration, workshop and writing of the paper. AS, CG, and SE advised on the development of the protocol, and data analysis. All authors participated in the StaRI international working group along with GP, BM, MG. HP wrote the initial draft of the paper, to which all the authors contributed. HP is the study guarantor.

**Funding:** The StaRI initiative and workshop was funded by contributions from the Asthma UK Centre for Applied Research [AC-2012-01]; Chief Scientist Office, Scottish Government Health and Social Care Directorates [PCRC\_A\_08\_01]; the Centre for Primary Care and Public Health, Queen Mary University of London; and with contributions in kind from the PRISMS team [NIHR HS&DR Grant ref: 11/1014/04]. ST was (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. AS is supported by the Farr Institute. The funding bodies had no role in the design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; nor in the decision to submit the manuscript for publication.

**Disclaimers:** The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

**Acknowledgements:** Members of the PRISMS team (Eleni Epiphaniou, Gemma Pearce, and Hannah Parke) supported the underpinning literature work, and the e-Delphi was handled by ClinVivo. We are grateful to a colleagues (implementation science experts, healthcare researchers, clinicians, PhD students) who reviewed the penultimate draft of the StaRI statement and provided a reality check and constructive feedback: Helen Ashdown, David Chambers, Louise Craig, Clarisse Dibao-Dina, Peter Hanlon, Roger Jones, Rachel Jordan, Chris del Mar, Brian McKinstry, Susan Morrow, John Ovreteit, David Price, Kamran Siddiqui, Rafael Stelmach, Paul Stephenson, Shaun Treweek, Bryan Weiner. We also thank Melissa Goodbourn and Allison Worth who arranged feedback from the Edinburgh Clinical Research Facility Patient Advisory Panel (Stephanie Ashby, Alison Williams) and Steven Towndrow who co-ordinated feedback from the Patient and Public Involvement representatives of the NIHR CLAHRC North Thames.

**Data sharing:** No additional data available

References

1. Harvard Catalyst. *Clinical and Translational Research Spectrum*. Available from <https://catalyst.harvard.edu/pathfinder> (Accessed June 2016)

2. Pinnock H, Epiphaniou E, Pearce G, et al. Implementing supported self-management for asthma: a systematic review of implementation studies. *BMC Medicine* 2015;13:127

3. Rycroft-Malone J, Burton CR. Is it time for standards for reporting on research about implementation? *Worldviews Evid Based Nurs* 2011;8:189-90

4. Chalkidou K, Anderson G. *Comparative Effectiveness Research: International Experiences and Implications for the United States*. Available from [http://www.nihcm.org/pdf/CER\\_International\\_Experience\\_09.pdf](http://www.nihcm.org/pdf/CER_International_Experience_09.pdf) (Accessed June 2016)

5. Pinnock H, Barwick M, Carpenter C, et al, for the StaRI team. Standards for Reporting Implementation Studies (StaRI) statement. **Statement submitted to BMJ**

6. Moher D, Schulz KF, Simera I, et al. Guidance for Developers of Health Research Reporting Guidelines. *PLoS Med* 2010;7:e1000217

7. Pinnock H, Taylor S, Epiphaniou E, et al. *Developing Standards for Reporting Phase IV Implementation studies*. Available from <http://www.equator-network.org/wp-content/uploads/2013/09/Proposal-for-reporting-guidelines-of-Implementation-Research-StaRI.pdf> (Accessed June 2016)

8. Pinnock H, Epiphaniou E, Sheikh A, et al. Developing Standards for Reporting Implementation studies (StaRI): an e-Delphi. *Implement Sci* 2015;10:42

9. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50

10. Foy R, Sales A, Wensing M, et al. Implementation science: a reappraisal of our journal mission and scope. *Implement Sci* 2015;10:51

- 1  
2  
3 11. Eccles MP, Armstrong D, Baker R, et al. An implementation research agenda. *Implement Sci*  
4  
5 2009;4:18  
6
- 7 12. Brownson RC, Colditz GA, Proctor EK (eds) *Dissemination and implementation research in health:*  
8  
9 *translating science into practice*. New York: Oxford University Press 2012  
10
- 11 13. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new  
12  
13 Medical Research Council guidance. London: MRC: 2008. Available from  
14  
15 [www.mrc.ac.uk/complexinterventionsguidance](http://www.mrc.ac.uk/complexinterventionsguidance) [accessed June 2016]  
16  
17
- 18 14. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation Hybrid Designs: Combining  
19  
20 Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health  
21  
22 Impact. *Medical Care* 2012;50:217-226  
23
- 24 15. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying  
25  
26 and reporting. *Implement Sci* 2013;8:1–11  
27
- 28 16. Rabin BA, Brownson RC. *Developing the terminology for dissemination and implementation*  
29  
30 *research*. In Brownson RC, Colditz GA, Proctor EK (Eds) *Dissemination and implementation*  
31  
32 *research in health*. New York; Oxford University Press: 2012  
33  
34
- 35 17. Proctor E, Brownson RC. *Measurement issues in dissemination and implementation research*. In  
36  
37 Brownson RC, Colditz GA, Proctor EK (Eds) *Dissemination and implementation research in health*.  
38  
39 New York: Oxford University Press 2012  
40  
41
- 42 18. Pinnock H, Adlem L, Gaskin S, et al. Accessibility, clinical effectiveness and practice costs of  
43  
44 providing a telephone option for routine asthma reviews: Phase IV controlled implementation  
45  
46 study. *Br J Gen Pract* 2007;57:714-722  
47
- 48 19. Kilbourne AM, Almirall D, Eisenberg D, et al. Protocol: Adaptive Implementation of Effective  
49  
50 Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced  
51  
52 implementation strategy to improve outcomes of a mood disorders program. *Implement Sci*  
53  
54 2014;9:132  
55  
56  
57  
58  
59  
60

20. Rycroft-Malone J, Seers K, Crichton N, et al. A pragmatic cluster randomised trial evaluating three implementation interventions. *Implement Sci* 2012;7:80

21. Aspy CB, Mold JW, Thompson DM, et al. Integrating Screening and Interventions for Unhealthy Behaviors into Primary Care Practices. *Am J Prev Med* 2008;35(5S):S373–S380

22. Bosworth HB, DuBard A, Ruppenkamp J, et al. Evaluation of a self-management implementation intervention to improve hypertension control among patients in Medicaid. *Transl Behav Med* 2011;1:191-199

23. Guyatt GH, Oxman AD, Schünemann HJ, et al. GRADE guidelines: A new series of articles in the Journal of Clinical Epidemiology. *J Clin Epidemiol* 2010;64:380–382

24. van Dijk-de Vries A, van Bokhoven MA, Terluin B, et al. Integrating nurse-led Self-Management Support (SMS) in routine primary care: design of a hybrid effectiveness-implementation study among type 2 diabetes patients with problems of daily functioning and emotional distress: a study protocol. *BMC Fam Pract* 2013;14:77

25. Sämann A, Lehmann T, Kloos C, et al. Flexible, intensive insulin therapy and dietary freedom in adolescents and young adults with type 1 diabetes: a prospective implementation study. *Diabet Med* 2008;25:592– 6

26. Emond YEJMM, Calsbeek H, Teerenstra S, et al. Improving the implementation of perioperative safety guidelines using a multifaceted intervention approach: protocol of the IMPROVE study, a stepped wedge cluster randomized trial. *Implement Sci* 2015;10:3

27. Campbell MK, Piaggio G, Elbourne DR, et al, for the CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661

28. Zwarenstein M, Treweek S, Gagnier JJ, et al, for the CONSORT and Pragmatic Trials in Healthcare (Practihc) groups. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008;337:a2390

29. von Elm E, Altman DG, Egger M, et al, for the STROBE initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;61:344-9
30. Nicholls SG, Quach P, von Elm E, et al. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement: Methods for Arriving at Consensus and Developing Reporting Guidelines. *PLoS ONE* 2015;10:e0125620
31. Jarlais DCD, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND Statement. *Am J Public Health* 2004;94:361-6
32. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19:349-357
33. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687
34. Davidoff F, Batalden P, Stevens D, et al. Publication guidelines for quality improvement studies in health care: evolution of the SQUIRE project. *Qual Saf Health Care* 2008;17:i3-9
35. Musacchio N, Lovagnini Scher A, et al. Impact of a chronic care model based on patient empowerment on the management of Type 2 diabetes: effects of the SINERGIA programme. *Diabet Med* 2011;28:724-730
36. Senior PA, MacNair L, Jindal K. Delivery of multifactorial interventions by nurse and dietitian teams in a community setting to prevent diabetic complications: a quality-improvement report. *Am J Kidney Dis* 2008; 51: 425-434
37. Rycroft-Malone J, Seers K, Chandler J, et al. The role of evidence, context, and facilitation in an implementation trial: implications for the development of the PARIHS framework. *Implement Sci* 2013;8:28
38. Green LW, Glasgow RE. Evaluating the Relevance, Generalization, and Applicability of Research: Issues in External Validation and Translation Methodology. *Eval Health Prof* 2006;29:126



39. Edward N, Barker PM. The importance of context in implementation research. *J Acquir Immune Defic Syndr* 2014;67 Suppl 2:S157-162

40. Prasad V, Ioannidis JPA. Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. *Implement Sci* 2014;9:1

41. Montini T, Graham ID. “Entrenched practices and other biases”: unpacking the historical, economic, professional, and social resistance to de-implementation. *Implement Sci* 2015;10:24

42. Consolidated Framework for Implementation Research. CFIR Constructs. Available from <http://cfirguide.org/index.html> (Accessed June 2016)

43. Warren CE, Mayhew SH, Vassall A, et al. Study protocol for the Integra Initiative to assess the benefits and costs of integrating sexual and reproductive health and HIV services in Kenya and Swaziland. *BMC Public Health* 2012;12:973

44. Cully JA, Armento MEA, Mott J, et al. Brief cognitive behavioral therapy in primary care: a hybrid type 2 patient-randomized effectiveness-implementation design. *Implement Sci* 2012;7:64

45. Cully JA, Paukert A, Falco J, et al. Cognitive-behavioral therapy: innovations for cardiopulmonary patients with depression and anxiety. *Cogn Behav Pract* 2009;16:394-407

46. Michie S, Fixsen DL, Grimshaw JM, et al. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implement Sci* 2009;4:1–6

47. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implement Sci* 2010;5:1–6

48. Hoffmann TC, Erueti C, Glasziou PP. Poor description of non-pharmacological interventions: analysis of consecutive sample of randomised trials. *BMJ* 2013;347:f3755

49. Cochrane Effective Practice and Organisation of Care Review Group. *Data Collection Checklist*. 2002. Available from <http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/datacollectionchecklist.pdf> (Accessed June 2016)

50. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci* 2015;10:21
51. Albrecht L, Archibald M, Arseneau D, et al. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implement Sci* 2013;8:52
52. Glaziou P, Chalmers I, Altman DG, et al. Taking healthcare interventions from trial to practice. *BMJ* 2010;341:c3852
53. Perara R, Heneghan C, Yudkin P. Graphical method for depicting randomized trials of complex interventions. *BMJ* 2007;334:127-129
54. Hooper R, Froud RJ, Bremner SA, et al. Cascade diagrams for depicting complex interventions in randomised trials. *BMJ* 2013;347:f6681
55. Ogrinc G, Davies L, Goodman D, et al. SQUIRE 2.0 (Standards for QQuality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf* 2015;46:501-7
56. Möhler R, Bartoszek G, Köpke S, et al. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CRedeCI): guideline development. *Int J Nurs Stud* 2012;49:40-46
57. Proctor EK, Landsverk J, Aarons G, et al. Implementation Research in Mental Health Services: an Emerging Science with Conceptual, Methodological, and Training challenges. *Adm Policy Ment Health* 2009;36:24-34
58. Proctor E, Silmere H, Raghavan R, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Adm Policy Ment Health* 2011;38:65-76
59. Been JV, Nurmatov UB, Cox B, et al. Effect of smoke-free legislation on perinatal and child health: a systematic review and meta-analysis. *Lancet* 2014;383:1549-60

60. Hulscher M, Laurant M, Grol R. Process evaluation of implementation strategies, in Improving Patient Care: The Implementation of Change in Health Care, Second Edition (eds R. Grol, M. Wensing, M. Eccles and D. Davis), Oxford: John Wiley & Sons Ltd 2013

61. Moore G, Audrey S, Barker M, et al, for the MRC Population Health Science Research Network. Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance. *BMJ* 2015;350:h1258

62. Stetler C, Legro MW, Wallace CM, et al. The role of formative evaluation in implementation research and the QUERI experience. *J Gen Intern Med* 2006;21 Suppl 2: S1-8

63. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1922-1927

64. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations, *Milbank Q* 2004;82:581-629

65. Greenhalgh T. Role of routines in collaborative work in healthcare organisations. *BMJ* 2008;337:a2448

66. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC Health Serv Res* 2006;6:86

67. Grant A, Treweek S, Dreischulte T, et al. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials* 2013;14:15

68. Saldana L. The stages of implementation completion for evidence-based practice: protocol for a mixed methods study. *Implement Sci* 2014;9:43

69. Michie S, Johnston M, Abraham C, et al. on behalf of the “Psychological Theory” Group. Making psychological theory useful for implementing evidence-based practice; a consensus approach. *Qual Saf Health Care* 2005;14:26–33

70. Mukuria C, Brazier J, Barkham M, et al. Cost-effectiveness of an Improving Access to Psychological Therapies service. *Br J Psychiatry* 2013;202:220–227

- 1  
2  
3 71. Husereau D, Drummond M, Petrou S, et al, on behalf of the CHEERS Task Force. Consolidated  
4  
5 Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ* 2013;346:f1049  
6  
7 72. Sullivan SD, Mauskopf JA, Augustovski F, et al. Principles of good practice for budget impact  
8  
9 analysis II: Report of the ISPOR Task Force on Good Research Practices – Budget Impact  
10  
11 Analysis. *Value Health* 2014;17:5-14  
12  
13 73. Cabinet Office. A guide to social return on investment 2012. Available from:  
14  
15 [https://www.bond.org.uk/data/files/Cabinet\\_office\\_A\\_guide\\_to\\_Social\\_Return\\_on\\_Investment.](https://www.bond.org.uk/data/files/Cabinet_office_A_guide_to_Social_Return_on_Investment.pdf)  
16  
17 [pdf](https://www.bond.org.uk/data/files/Cabinet_office_A_guide_to_Social_Return_on_Investment.pdf) (last accessed June 2016)  
18  
19  
20 74. Gomes M, Grieve R, Nixon R, Edmunds WJ. Statistical methods for cost-effectiveness analyses  
21  
22 that use data from cluster randomized trials: a systematic review and checklist for critical  
23  
24 appraisal. *Medical Decision Making* 2012; 32: 209-220  
25  
26 75. Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled  
27  
28 trials. The CONSORT statement. *JAMA* 1996;276:637-9  
29  
30 76. Cresswell JW, Plano-Clark VL. Designing and conducting mixed methods research 2011.  
31  
32 California; Sage Publications: 2011  
33  
34 77. Andersson N, Cockcroft A, Thabane L, et al. HIV prevention in favour of the choice-disabled in  
35  
36 southern Africa: study protocol for a randomized controlled trial. *Trials* 2013;14:274  
37  
38 78. Cleland JA, Hall S, Price D, et al. An exploratory, pragmatic, cluster randomised trial of practice  
39  
40 nurse training in the use if asthma action plans. *Prim Care Respir J* 2007;16:311-318  
41  
42 79. Homer CJ, Forbes P, Horvitz L, et al. Impact of a quality improvement program on care and  
43  
44 outcomes for children with asthma. *Arch Pediatr Adolesc Med* 2005;159:464-469  
45  
46 80. Jordan RE, Lancashire RJ, Adab P. An evaluation of Birmingham Own Health telephone care  
47  
48 management service among patients with poorly controlled diabetes. A retrospective  
49  
50 comparison with the General Practice Research Database. *BMC Public Health* 2011;11:707  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

81. Stevens DP, Bowen JL, Johnson JK, et al. A multi-institutional quality improvement initiative to transform education for chronic illness care in resident continuity practices. *J Gen Intern Med* 2010;25 Suppl 4:S574-580

82. Dettori N, Flook BN, Pessl E, et al. Improvements in care and reduced self-management barriers among rural patients with diabetes. *J Rural Health* 2005;21:172-177

83. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program using the consolidated framework for implementation research (CFIR). *Implement Sci* 2013;8:51

84. Kind AJH, Brenny-Fitzpatrick M, Leahy-Gross K, et al. Harnessing Protocolized Adaptation in Dissemination: Successful Implementation and Sustainment of the Veterans Affairs Coordinated-Transitional Care Program in a Non-Veterans Affairs Hospital. *J Am Geriatr Soc* 2016;64:409-416

85. Murphy SM, Edwards RT, Williams N, et al. An evaluation of the effectiveness and cost effectiveness of the National Exercise Referral Scheme in Wales, UK: a randomised controlled trial of a public health policy initiative. *J Epidemiol Community Health* 2012;66:745e753

86. Bertoni AG, Bonds DE, Chen H, et al. Impact of a Multifaceted Intervention on Cholesterol Management in Primary Care Practices: Guideline Adherence for Heart Health Randomized Trial. *Arch Intern Med* 2009;169:678–686

87. Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a randomised controlled trial be? *BMJ* 2004;328:1561–3

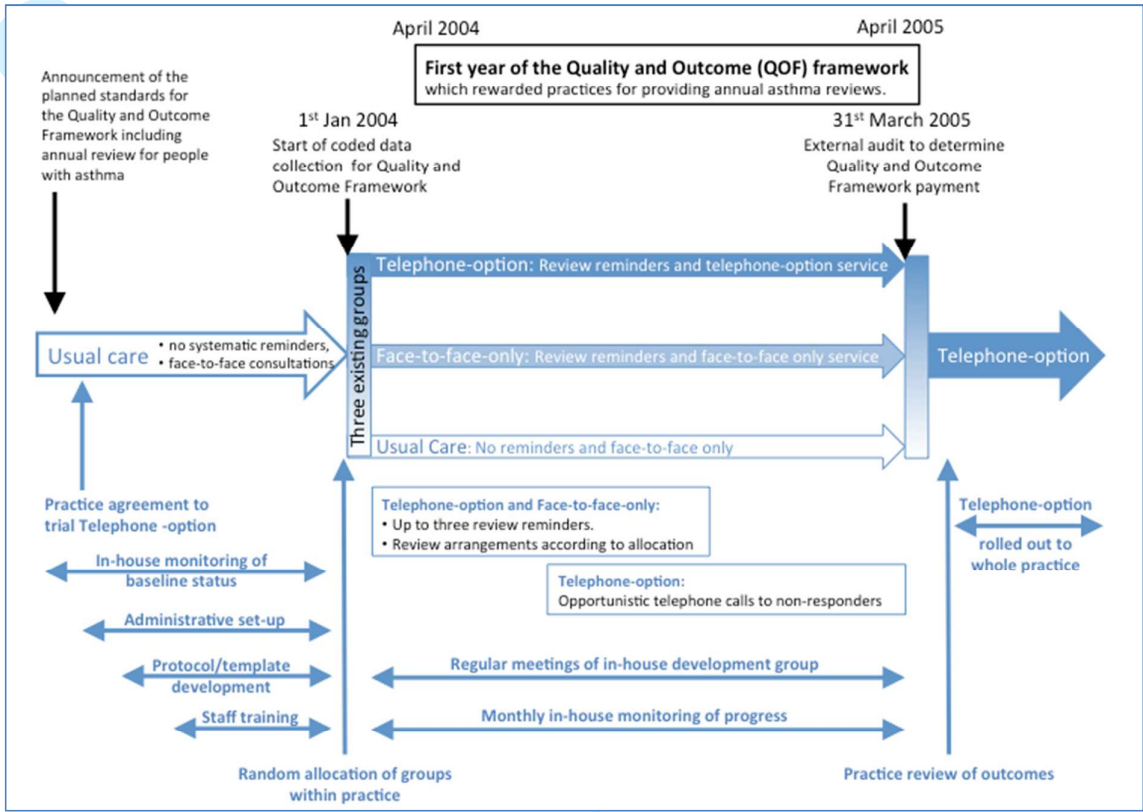
88. Dane AV, Schneider BH. Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clin Psychol Rev* 1998;18:23-45

89. Bumbarger B, Perkins D. After randomised trials: issues related to dissemination of evidence-based interventions, *J Child Serv* 2008;3:55-64

90. Stirman SW, Miller CJ, Toder K, et al. Development of a framework and coding system for modifications and adaptations of evidence-based interventions, *Implement Sci* 2013;8:65

- 1  
2  
3 91. Gearing RE, El-Bassel N, Ghesquiere A, et al. Major ingredients of fidelity: A review and scientific  
4  
5 guide to improving quality of intervention research implementation. *Clin Psychol Rev*  
6  
7 2011;31:79–88  
8  
9 92. Raebel MA, Carroll NM, Kelleher JA, et al. Randomized trial to improve prescribing safety during  
10  
11 pregnancy. *J Am Med Inform Assoc* 2007;4:440-450  
12  
13 93. Goldzweig CL, Orshansky G, Paige NM, et al. Electronic health record-based interventions for  
14  
15 improving appropriate diagnostic imaging: a systematic review and meta-analysis. *Ann Int Med*  
16  
17 2015;162:557-565  
18  
19 94. Souza NM, Sebaldt RJ, Mackay JA, et al for the CCDSS Systematic Review Team. Computerized  
20  
21 clinical decision support systems for primary preventive care: A decision-maker researcher  
22  
23 partnership systematic review of effects on process of care and patient outcomes. *Implement*  
24  
25 *Sci* 2011;6:87  
26  
27 95. Hemens BJ, Holbrook A, Tonkin M, et al, for the CCDSS Systematic Review Team. Computerized  
28  
29 clinical decision support systems for drug prescribing and management: A decision-maker-  
30  
31 researcher partnership systematic review. *Implement Sci* 2011;6:89  
32  
33 96. Docherty M, Smith R. The case for structuring the discussion of scientific papers. *BMJ* 1999;  
34  
35 8;318:1224-5  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Figure 1.** Example of a timeline describing an implementation strategy (Compiled from Pinnock et al description of the implementation of a telephone service for providing asthma reviews.[18])



Note: The three-arm implementation study is illustrated in the centre of this schema with the preceding usual care, randomisation on 1<sup>st</sup> January 2004, the 15-month intervention and subsequent roll-out. The context (specifically the introduction of the Quality and Outcome Framework) is shown at the top of the schema. Below the three-arms of the study are the components of the implementation strategy from set-up and training, on-going service provision and maintenance, and adoption into routine practice.

**Figure 2. Summary of outcomes and the related items in the StaRI checklist**

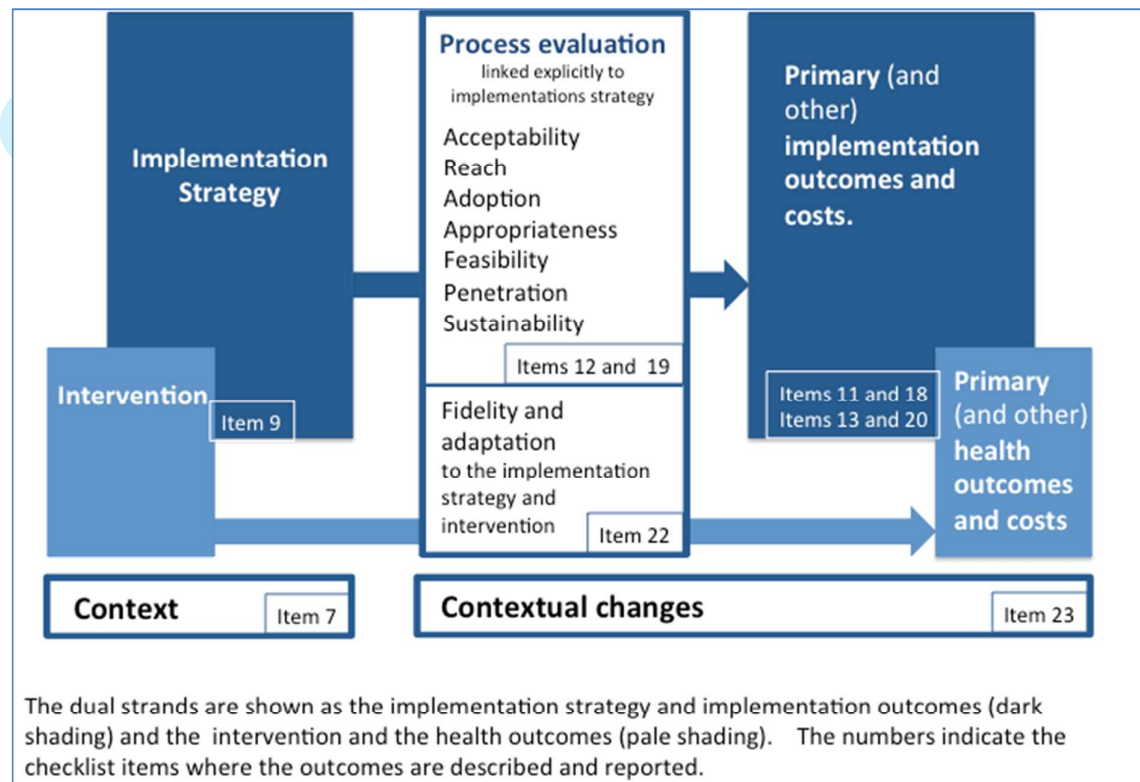




Table 1. Terminology, definitions and resources

Term used in this paper	Definition	Alternative terminology and similar concepts
Implementation strategy	Sources of information  Methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical programme or practice.[14,15,16]  Exemplar resources: Consolidated Framework For Implementation Research (CFIR) <a href="http://www.cfirguide.org/imp.html">http://www.cfirguide.org/imp.html</a> Dissemination and implementation models <a href="http://www.dissemination-implementation.org/index.aspx">http://www.dissemination-implementation.org/index.aspx</a>	Implementation approach Implementation programmes Implementation process Implementation intervention
Implementation outcome	Process or quality measures to assess the impact of the implementation strategy, such as adherence to a new practice, acceptability, feasibility, adaptability, fidelity, costs & returns.[14,58]	Endpoint
Intervention	The evidence-based practice, programme, policy, process, or guideline recommendation that is being implemented (or de-implemented).[12] In the context of healthcare this might be a preventive, diagnostic or therapeutic clinical practice, delivery system change, or public health activity being implemented to improve patient's outcomes, system quality and efficiency, or population health.	Treatment Evidence-based intervention
Health outcome	Patient-level health outcomes for a clinical intervention, such as symptoms or mortality; or population-level health status or indices of system function for a system/ organisational-level intervention.[14]	Health status Client outcome
Logic pathway	The manner in which the implementation strategy is hypothesised to operate.	Logic model Causal pathway/ model Mechanisms of action /impact Theory of change Driver diagrams Cause-and-effect diagram (Ishikawa, fishbone diagrams) Donabedian model
	Exemplar resource: Logic models: <a href="https://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide">https://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide</a>	
Process evaluation	A study that aims to understand the functioning of an intervention, by examining its implementation, mechanisms of impact, and contextual factors. Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation.[61] Process evaluation aims to describe the strategy for change as planned, the strategy as delivered, the actual exposure of the target population to the activities that are part of the strategy, and the experiences of the people exposed.[60] [Formative evaluation] is a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts.[62]	Formative evaluation
	Exemplar resource: Process evaluation of complex interventions. Available from <a href="https://www.ioe.ac.uk/MRC_PHSRN_Process_evaluation_guidance_final(2).pdf">https://www.ioe.ac.uk/MRC_PHSRN_Process_evaluation_guidance_final(2).pdf</a>	
'Barriers and facilitators'	Aspects related to the individual (i.e., healthcare practitioner or healthcare recipient) or to the organisation that 'determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort'.[50]	Drivers Mediators, Moderators Contextual factors Enablers Organisational conditions for change

**Table 2. Standards for Reporting Implementation Studies: the StaRI checklist**

Report the following:		"Implementation strategy" refers to how the intervention was implemented. "Intervention" refers to the healthcare or public health intervention that is being implemented.	
Checklist item		Implementation Strategy	Intervention
<b>Title</b>	<b>1</b>	Identification as an implementation study, and description of the methodology in the title and/or keywords	
<b>Abstract</b>	<b>2</b>	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.	
<b>Introduction</b>	<b>3</b>	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.	
	<b>4</b>	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
<b>Aims and objectives</b>	<b>5</b>	The aims of the study, differentiating between implementation objectives and any intervention objectives.	
<b>Methods: description</b>	<b>6</b>	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	<b>7</b>	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).	
	<b>8</b>	The characteristics of the targeted 'site(s)' (e.g. locations/personnel/resources etc.) for implementation and any eligibility criteria.	The population targeted by the intervention and any eligibility criteria.
	<b>9</b>	A description of the implementation strategy	A description of the intervention
	<b>10</b>	Any sub-groups recruited for additional research tasks, and/or nested studies are described	
<b>Methods: evaluation</b>	<b>11</b>	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
	<b>12</b>	Process evaluation objectives and outcomes related to the mechanism(s) through which the strategy is expected to work	

	13	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	Methods for resource use, costs, economic outcomes and analysis for the intervention
	14	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)	
	15	Methods of analysis (with reasons for that choice)	
	16	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks	
Results	17	Proportion recruited and characteristics of the recipient population for the implementation strategy.	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
	18	Primary and other outcome(s) of the implementation strategy.	Primary and other outcome(s) of the Intervention (if assessed).
	19	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work	
	20	Resource use, costs, economic outcomes and analysis for the implementation strategy	Resource use, costs, economic outcomes and analysis for the intervention
	21	Representativeness and outcomes of subgroups including those recruited to specific research tasks	
	22	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	Fidelity to delivering the core components of intervention (where measured).
	23	Contextual changes (if any) which may have affected outcomes	
	24	All important harms or unintended effects in each group.	
Discussion	25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications.	
	26	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability).	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability).
General	27	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest.	

Note: A key concept is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist. The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. Whilst all items are worthy of consideration, not all items will be applicable to or feasible within every study.

**Table 3. Example of a table describing\* an implementation strategy** compiled from Kilbourne et al description of the implementation of Life Goals (LG): a clinical intervention for patients with mood disorders.[19]

Name of discrete strategies	Assess for readiness to adopt LG intervention. Recruit champions and train for leadership.	Develop and distribute educational materials, manuals, toolkits, and an implementation blueprint.	Educational meetings, outreach visits, clinical supervision, technical assistance, ongoing consultation.	Facilitation (external & internal) and continuous implementation advice.
<b>Actors</b>	Investigators, representatives from practices & community.	Investigators, trainers and LG providers designated at each site.	Trainers and LG providers.	Investigators, external & internal facilitators (EF & IF), LG providers.
<b>Actions</b>	<u>Pre-implementation meetings</u> with site representatives for in-service marketing and dissemination of the LG program: overview of LG evidence, benefits of LG, and how to implement LG. Identify in each site at least one <u>potential LG providers</u> with a mental health background and internal Facilitators. Identify champions. Assess readiness, barriers and facilitators.	<u>Packaging LG protocol &amp; provider manual</u> (identifying candidate patients; scripts for session & follow-up calls; registry for tracking patients' progress). Design implementation: <u>Implementation manual</u> describing the "Replicating Effective Programs" (REP) package. <u>Patients' workbook</u> (exercises on behavior change goals, symptom assessment, coping strategies...).	<u>Training for LG providers</u> : evidence behind LG, core elements & step-by-step walk through LG components; patient tracking & monitoring over time & continuous education via LG website. <u>Program assistance and LG uptake monitoring</u> via LG website, support by study program assistant, biweekly monitoring form, feedback reports & newsletters.	<u>Initiation and benchmarking</u> : EF & LG providers identify barriers, facilitators, and goals. <u>Leveraging</u> : IF & LG providers identify priorities, other LG champions, and added value of LG to site providers. <u>Coaching</u> : IF, EF, & LG providers phone to develop rapport & address barriers. <u>Ongoing marketing</u> : IF, leaders & LG providers summarize progress and develop business plans.
<b>Targets</b>	Awareness of evidence-based interventions, engagement, and settings' readiness to change.	Environmental context and resources, information, and access to interventions.	Build knowledge, beliefs, skills, and capabilities: problem solving, decision making, interest.	Strengths and influences of LG provider. Measurable objectives and outcomes in implementing LG.
<b>Temporality</b>	1 <sup>st</sup> step: pre-implementation	2 <sup>nd</sup> step: REP implementation	3 <sup>rd</sup> step: training and start up	4 <sup>th</sup> step: Maintenance/evolution
<b>Dose</b>	One Informative meeting.	For continuous use with every patient, as needed.	1-day 8 hour training program + continuous assistance & monitoring	2-day training program EF and continuous facilitation activities
<b>Implementation outcomes addressed / affected</b>	Barriers, facilitators, specific uptake goals; organizational factors: i.e. Implementation Leadership Scale, Implementation Climate Scale, resources, staff turnover, improved organizational capacity to implement, organizational support...	Organizational factors associated to implementation. Quality of the supporting materials, packaging, and bundling of the intervention. Association of available materials' quality with actual implementation. Providers' knowledge, skills trust	RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, & Maintenance) and LG performance measures of routine clinical care process: i.e. sessions completed by patient, percentage completing 6 sessions...	IF, EF & LG provider's perceptions, strengths & opportunities to influence site activities and overcome barriers. Adaptation & fidelity monitoring: i.e. number of meetings, opportunities to leverage LG uptake. Quality & costs.
<b>Theoretical justification</b>	CDC's Research to Practice Framework. Social learning theory	REP framework & implementation strategy for community-based settings (includes Rogers' Diffusion of Innovations and Social Learning Theory)		Adaptive implementation. PARIHS Framework.

\*Using Proctor et al's framework [15]



Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. xxxxxxxxxx

A detailed Explanation and Elaboration document is available [here](#) which provides the rationale and exemplar text for all these items.

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item	Reported on page #	Implementation Strategy	Reported on page #	Intervention
		"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract				
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction				
Introduction	3	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	5		The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6		The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7		The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	8		The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9		A description of the implementation strategy		A description of the intervention
Sub-groups	10		Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11		Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12		Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13		Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14		Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15		Methods of analysis (with reasons for that choice)		
Sub-group analyses	16		Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	17		Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18		Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19		Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20		Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21		Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	22		Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23		Contextual changes (if any) which may have affected outcomes		
Harms	24		All important harms or unintended effects in each group		
Discussion					
Structured discussion	25		Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26		Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27		Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		



## Web-references

- w1 Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC, USA: National Academies Press; 2001
- w2 NHS England. NHS England Research and Development Strategy 2013 – 2018: *Research is everybody's business*. Available <http://www.invo.org.uk/wp-content/uploads/2014/02/NHS-England-Research-Strategy-Consultation.pdf> (Accessed June 2016)
- w3 National Health and Medical Research Council. *How to put the evidence into practice: implementation and dissemination strategies*. Commonwealth of Australia: 2000. Available from [https://www.nhmrc.gov.au/files\\_nhmrc/publications/attachments/cp71.pdf](https://www.nhmrc.gov.au/files_nhmrc/publications/attachments/cp71.pdf) (Accessed June 2016)
- w4 Harvard Catalyst. *Clinical and Translational Research Spectrum*. Available from <https://catalyst.harvard.edu/pathfinder> (Accessed June 2016)
- w5 Westfall JM, Mold J, Fagnan L. Practice-based research - "Blue Highways" on the NIH roadmap. *JAMA* 2007;297:403-6
- w6 Grimshaw J, Eccles M, Thomas R, et al. Toward evidence-based quality improvement: Evidence (and its limitations) of the effectiveness of guideline dissemination and implementation strategies 1966–1998. *J Gen Intern Med* 2006;21:S14–S20
- w7 Newhouse R, Bobay K, Dykes PC, et al. Methodology issues in implementation science. *Med Care* 2013;51(Suppl 2):S32-40
- w8 Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;276:637-9
- w9 Plint AC, Moher D, Morrison A, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med J Aust* 2006;185:263-267
- w10 Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA* 2001;285:1992e5
- w11 Kane RL, Wang J, Garrard J. Reporting in randomized clinical trials improved after adoption of the CONSORT statement. *J Clin Epidemiol* 2007;60:241-249
- w12 Eccles MP, Armstrong D, Baker R, et al. An implementation research agenda. *Implement Sci* 2009;4:18
- w13 Prasad V, Ioannidis JPA. Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. *Implement Sci* 2014;9:1
- w14 Blase KA, Fixsen DL, Sims BJ, Ward CS. *Implementation Science – Changing Hearts, Minds, Behavior, and Systems to Improve Educational Outcomes*. Paper presented at the Wing Institute's Ninth Annual Summit on Evidence-Based Education, Berkeley, CA 2015
- w15 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1922-1927
- w16 May, C., & Finch, T. (2009). Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology*, 43(3), 535–554



w17 McMullen H, Griffiths C, Leber W, Greenhalgh T. Explaining high and low performers in complex intervention trials: a new model based on diffusion of innovations theory. *Trials*. 2015;16:242

w18 Greenhalgh T. Role of routines in collaborative work in healthcare organisations. *BMJ* 2008;337:a2448

w19 Green LW, Glasgow RE. Evaluating the Relevance, Generalization, and Applicability of Research: Issues in External Validation and Translation Methodology. *Eval Health Prof* 2006;29;126

w20 Ogrinc G, Davies L, Goodman D, et al. SQUIRE 2.0 (Standards for QQuality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf* 2015;46:501–7

w21 Hales S, Leshner-Trevino A, Ford N, et al. Reporting guidelines for implementation and operational research. *Bull World Health Org* 2016;94:58-64

w22 Moher D, Schulz KF, Simera I, et al. Guidance for Developers of Health Research Reporting Guidelines. *PLoS Med* 2010;7:e1000217

w23 Pinnock H, Taylor S, Epiphaniou E, et al. *Developing Standards for Reporting Phase IV Implementation studies*. Available from <http://www.equator-network.org/wp-content/uploads/2013/09/Proposal-for-reporting-guidelines-of-Implementation-Research-StaRI.pdf> (Accessed June 2016)

w24 Proctor E, Brownson RC. *Measurement issues in dissemination and implementation research*. In Brownson RC, Colditz GA, Proctor EK (Eds) *Dissemination and implementation research in health*. New York; Oxford University Press: 2012

w25 Pinnock H, Adlem L, Gaskin S, et al. Accessibility, clinical effectiveness and practice costs of providing a telephone option for routine asthma reviews: Phase IV controlled implementation study. *Br J Gen Pract* 2007;57:714-722

w26 Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implement Sci* 2013;8:1–11

w27 Campbell MK, Piaggio G, Elbourne DR, et al, for the CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661

w28 von Elm E, Altman DG, Egger M, et al, for the STROBE initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;61:344-9

w29 Dane AV, Schneider BH. Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clin Psychol Rev* 1998;18:23-45

w30 Moore G, Audrey S, Barker M, et al, for the MRC Population Health Science Research Network. Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance. *BMJ* 2015;350:h1258

w31 Edward N, Barker PM. The importance of context in implementation research. *J Acquir Immune Defic Syndr* 2014; 67 Suppl 2: S157-162

w32 Montini T, Graham ID. “Entrenched practices and other biases”: unpacking the historical, economic, professional, and social resistance to de-implementation. *Implement Sci* 2015; 10:24